AN OPEN CLINICAL TRIAL OF SIDDHA DRUG AKKINI CHOORANAM (INTERNAL) AND VEERA MEZHUGU (EXTERNAL) IN THE TREATMENT OF KUTHIKAAL VAATHAM (PLANTAR FASCIITIS)

The dissertation Submitted by

Dr. M. Padmavathi,

P.G.Scholar

Under the Guidance of

Dr. N.J. Muthukumar M.D(s),

Head of the Department

Department of Sirappu Maruthuvam.

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DECLARATION BY THE CANDIDATE

I hereby declare that this dissertation entitled "An Open Clinical trial of Siddha drug Akkini Chooranam (Internally) and Veera Mezhugu (Externally) in the treatment of Kuthikaal Vaatham" (Plantar Fasciitis) is a bonafide and genuine research work carried out by me under the guidance of **Dr. N.J. Muthukumar M.D(S)**, Head of the Department, Department of **Sirappu Maruthuvam**, National Institute of Siddha, Chennai -47, and the dissertation has not formed the basis for the award of any Degree, Diploma, Fellowship or other similar title.

Date:

Place: Chennai-47

Signature of the Candidate

Dr. M. PADMAVATHI

BONAFIDE CERTIFICATE

Certified that I have gone through the dissertation submitted by **Dr. M. Padmavathi, (Reg.No: 321413206)** a student of final year M.D(s), Branch-III, Department of **Sirappu Maruthuvam**, **National Institute of Siddha**, Tambaram Sanatorium, Chennai-47 and the dissertation work has been carried out by the individual only. This dissertation does not represent or reproduce the dissertation submitted and approved earlier.

Place: Chennai-47

Date:

Name and Signature of the Guide & HOD,

Department of Sirappu Maruthuvam,

National Institute of Siddha,

Tambaram Sanatorium,

Chennai-47

Forwarded by the Head of the Institution,

National Institute of Siddha,

Tambaram Sanatorium,

Chennai-47

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INTRODUCTION

INTRODUCTION

Siddha system of medicine is one of the ancient system of medicine. The *Siddhars* laid the foundation for this system of medicine. *Siddhars* were spiritual adepts who possessed the *Ashtma siddhi* (eight super natural powers). The scientific knowledge of ancient Siddhars is marvelous and awe-inspiring; and their works are objects of great admiration at present.

The Siddha system of medicine has been evolved from a study of the special characteristics of the physical constitution of the people. The medicine prescribed in that science are herbs, bulbs and roots endemic to the region of Tamil Nadu and in abundance and agreeable to the nature of the food suitable to their constitution and which the people are accustomed to.

According to this system of medicine, health is defined as the state of physical, psychological, social and spiritual component of a human being. All the objects in this world either living or non-living are composed of five elements (*IymBootham*) namely;

1.	Man	- Earth
2.	Neer	- Water
3.	Thee	- Fire
4.	Kaatru	- Air
5.	Aagayam	- Ether

Physical health of human body is maintain by the three basic vital forces (humours) namely *Vaatham*, *Pitham*, *Kabam* called *Uyirthathukkal* which are activated by the function of *Iymbootham* (Five elements).

When the above vital energy are affected or not in a balanced state they become *Kuttrams* which three disposes to diseases. The factors which affect this equilibrium are environment, climatic conditions, diet and abnormal physical activities etc.

Diet and lifestyle plays a major role in health. Siddha system of medicine also emphasizes the importance of diet and lifestyle by the way of Pathiyam and Apathyam i.e, Do's and Don'ts. To maintain a healthy life is based on the lifestyle, proper diet, normal habits, Yogasanas, Pranayamam etc.

In Siddha system the diseases are classified according to *Mukkutram* theory and diseases are 4448 in numbers.

There are many diseases commonly affecting the middle age and elderly people. One among them is *Kuthikaal Vaatham* which is mainly interfering with the principle function of locomotion in human being. In this disease commonly heel is involved and in later stage it makes discomfort and disability to the individual.

I have interested to try effective remedy to *Kuthikaal vaatham* as said in Siddha literatures with the application of basic principles of Siddha and also supporting by Modern parameters.

As per by the *T.V. Sambasivam Pillai*, Kuthikaal vaatham is a disease of the heel rendering one unable to rest on the heel owing to excessive neuralgic pain – Pododynia. Pain experienced in raising the toes and suddenly bringing the heels to the ground – Heel-Jar.

Kuthikaal Vaatham may be compared with signs and symptoms of Plantar fasciitis in modern science. Plantar fasciitis is an aseptic inflammation of plantar fascia. It is pain in the heel, which is more in the morning. It gradually subsides as the patients take a few steps. The pain increases on prolonged standing, walking etc. It affects people in their active period of life and causes embarrassment both physically and mentally.

It affects the both sex, approximately 10 % of general population particularly women in the age group between 40 and 60 years are mostly affected. The prevalence rates of plantar fasciitis among a population of runners have been shown to be between 4% and 22%.

The medicine choosen to this disease are *Akkini Chooranam* as Internal medicine and *Veera Mezhugu* as External application. In *Akkini chooranam*, most of the drugs having the actions of anti-inflammatory, anti-vaatha and analgesic properties. So I have choosen these drugs for my dissertation.

3

AIMS AND OBJECTIVES

AIM AND OBJECTIVES

AIM:

To evaluate the therapeutic efficacy of siddha drugs *Akkini Chooranam* (Internal) and *Veera Mezhugu* (External) for the treatment of *Kuthikaal Vaatham* (Plantar fasciitis).

OBJECTIVE:

Primary Objective:

To evaluate the efficacy of siddha drugs *Akkini chooranam* (Internal) and *Veera Mezhugu* (External) in reducing the pain and restricted movements in the treatment of *Kuthikaal Vaatham* (Plantar Fasciitis) through clinical study.

Secondary Objective:

To study the other associated factors such as age, sex, BMI and occupation.

REWIEW OF LITERATURE

SIDDHA ASPECT

SIDDHA ASPECT

The concepts of Siddha system are based on fundamental principles of five basic elements, 96- *Thathuvams*, Three vital energy and Seven *Thaathus* (physical constituents of the body).

Vaatham, Pitham, Kabam are called as three vital energy of the human body. When the hormony of the above said vital energy get deranged owing to a relative increase or decrease of one or more of the principle vital energy, disease is caused. The normal ratio of *Vaatham, Pitham, Kabam* are 1:1/2:1/4 respectively. It is explained in the following verse,

> "வழங்கிய வாதம் மாத்திரை யொன்றாகில் தழங்கிய பித்தந் தன்னிலரை வாசி அழங்குங் கபந்தா னடங்கியே காலோடில் பிறங்கிய சீவர்க்குப் பிசகொன்று மில்லையே'' - குணவாகட நாடி

The alteration in the normal ratio produces disease. The signs and symptoms are produced according to the particular deranged kuttrams.

KUTHIKAAL VAATHAM

A disease of the heel rendering one unable to rest on the heel owing to excessive neuralgic pain – Pododynia.

Pain experienced in raising the toes and suddenly bringing the heels to the ground – Heel-Jar.

-T.V. Sambasivam Pillai. (volume-2)

AETIOLOGY OF VAATHA DISEASES:

According to Yugi Vaithya Chinthamani

"என்னவே வாதந்தா னெண்ப தாகும் மிகுத்திலே மனிதா்களுக் கெய்து மாறு பின்னவே பொந்தனையே சோரஞ் செய்து பெரியோர்கள் பிராமணரைத் தூஷ் ணித்தும் வன்னவே வச்சொத்திற் சோரஞ் செய்து மாதாபிதா குருவை மறந்து பேர்க்கும் கன்னவே வேதத்தை நிந்தைசெய்த போக்குங் காயத்திற் கலந்திடுமே வாதந் தானே." "தானென்ற கசப்போடு துவா்ப்பு ரைப்பு சாதகமாய் மிஞ்சுகினுஞ் சமைத்த வன்னம் ஆனென்ற வாறினது பொசித்த லாலும் ஆகாத் தேறலது குடித்த லாலும் பானென்ற பகலுறக்க மிராவி ழிப்பு பட்டினியே மிகவுறுதல் பார மெய்தல் தேனென்ற மொழியாற் மேற் சிந்தை யாகில் சீக்கிரமாய் வாதமது செனிக்குந் தானே." "ஆணான வரன்றனௌயே மதியா மாந்தர் அகதிபர தேசியா்கட் கன்ன மீயாா் கோனான குரமொழியை மறந்த பேர்கள் கொலைகளவு பொய்காமங் குறித்த போக்கு ஊனான சடந்தன்னில் வாதம் வந்து உற்பவிக்கும் வேதத்தி லுண்மை தானே."

The above line indicates, those who disrespect the parents, teachers, insulting the elders, blaspheming the Holy books - having cruel in their thoughts daytime and sleeplesness at night will get Vaatha diseases. Increased intake of bitter, astringent, sour type of foods, increased intake of water, excessive starvation, increased sexual activities will produce Vaatha diseases.

According to the text 'Pararasasekaram'

தொழில் பொறுகைப்புக்கார்த் தல்துவர்த்தல் விஞ்சுகினுஞ்சோறும் பழையதாம் வரகு மற்றைப் பைந்தினை யருந்தி னாலும் எழில்பெறப் பகலு றங்கி இரவினி லுறங்கா தாலும் மழைநிகர் குழலி னாளே வாதங்கோ பிக்குங் காணே. காணவே மிகவுண் டாலுங் கருதுபட் டினிவிட் டா மானனை யார்கண் மோக மறக்கினு மிகுந்திட்டாலும் ஆணவ மலங்க டம்மை யங்ஙனே விடாத தாலும் வானுதன் மடநல் லாளே வாதங்கோ பிக்குங் காணே. பாரினிற் பயப்பட்டாலும் பலருடன் கோபித் தாலும் காரெனக் கருகி யோடிக் கழுமரத் துரத்தி ணாலும் ஏர்பெறு தனது நெஞ்சின் மிகத்துக்க மடைந்திட்டாலும் பாரியகாற்றி னாளும் படரினும் வாதங் காணும். காலங்கண் மாறி யுண்ணுங் காரியத் தாலுந் தண்ணீர் சாலவே யருந்தி ணலுஞ் சந்தியி லுட்கார்ந் தாலும் கோலமாம் புளிப்பு நெய்மைக் குறைவற வருந்தி னாலும் வாலவார் முலைநல் லாளேவாதமுற் பவிக்குங் காணே. உற்பவித் தெழுமப் போதே யுயாபுறத் துடியைப் பற்றித் தெற்பறக் குடைந்து நோவுஞ் செய்துமேல நோக்கு மாகில் விற்பொலி நுதலி னாளே மேலிடுங் குணங்க டம்மில் சொற்பெறு வாதம் தோன்றுமென் றறிந்து கொள்க தெரிந்துமுன் சொன்ன வண்ணஞ் செய்யகா லடியைப் பற்றி மாந்தனைப் போற்றி மிர்த்து மற்றுமேல் நோக்கு மாகில் அரன்றனைத் துதியா மாந்த ரனுசரிக் கின்ற கோயில் சரிந்திடுங் குழலாய் வாதங் குடிபுகுஞ் சாற்றுங் காலே.

According to the text, indicates the intake of acrid, bitter taste, pungent content foods, intake of grains, sleep in day time and instead loss of sleep in night time. Increased intake of food, frequent exposure to starvation, excessive sexual activities, increased fear, increased anger, increased sadness, and high exposure to air, alteration in taking of diet timings will produce Vaatha diseases.

In the text 'Agathiyar Kanma Kaandam'

"நூலென்ற வாதம்வந்த வகை தானேது நுண்மையாய்க் கன்மத்தின் வகையைக்கேளு காலிலே தோன்றியது கடுப்பதேது கைகாலில் முடக்கியது வீக்கமேது கோலிலே படுக்கின்ற விருட்சமான குழந்தைமரந் தனைவெட்டல் மேல்தோல் சீவல்

நாலிலேசீவ செந்து கால் முறித்தல்

நல்லகொம்பு தழைமுறித்தல் நலித்தல் காணே."

The above text indicates Cutting young trees, peeling the wood bark, fracturing the legs of animals will produce Vaatha diseases.

According to the text Sarabenthirar Vaithiya Muraigal- Vaatha Rokha Sikitchai

- Consuming low quantity of food
- Sexual indulgence
- Decreased sleep
- > When more or less in taking purgation, emetics
- Taking more times of Blood letting therapy
- Doing heavy work
- ➢ Weakness due to sorrow, diseases, worries
- Control of reflexes like feaces, urination
- Conversion of undigested food juices into toxic substances(aamam)
- > Trauma
- Control of hunger
- ➢ Injuries in uyirnilaigal
- ► Falling down from vehicle
- Doing heavy works

All these activities lead to the low level of saaram in ducts. So as to compensate this more of vaayu's were produced and affect one or more organs.

FACTORS THAT INFLUENCE THE VAATHA TYPE OF DISEASE:

Seasons which deranges Vaatham :

In Muthuvenil kaalam, the solar radiation increases the evaporation of water content from the earth in turn produces dryness. Similarly the dryness is produced in our body and causes vaatha diseases.

A) Diets which deranges Vaatham:

According to the text 'Sababathi Kaiyedu'

"வளி தரு காய்கிழங்கு வரைவிலா தமிலல் கோழை புளி தயிர் போன்மிகுக்கு முறையிலா வுண்டி கோடல் குளிர்தரு வளியிற் றேகங் குனிப்புற வுலவல் பெண்டிர் குளிதரு மயக்கம் பெற்றோர் கடிசெயல் கருவியாமல்." The excessive intake of tubers food items, irregularity in taking foods, consume curd, acrid food items, higher exposure to wind, living in higher altitudes, increased sexual desire, and increased exposure to chill weather will aggravate Vaatha diseases.

B) Habitual characters which deranges Vaatham:

InTheraiyar vagadam,

"வெய்யிலில் நடக்கைsயாலும் மிகத்தண்ணீர் குடிக்கையாலும் செய்யிழை மகளினரைச் சேர்ந்தனுப விக்கையாலும் பையனே உண்மையாலும் பாகற்காய் தின்கையாலும் தையலே வாதரோகம் சனிக்குமென் றறிந்து கொள்ளே."

Walking in direct exposure to sunlight, excessive intake of water, sexual indulgence, intake of bitter guard will leads to Vaatha diseases.

SEATS OF THE THREE HUMORS:

"வளிமுதலா யெண்ணியமுக் குற்ற மெல்லாம் வாழ்வதெனும் தேகமுற்றும் பம்பிப் பரந்து தெளிவுறச் சாற்றும்நாபிக் குக்கீழ் வாதம் தீயின்கூ றாமழலோ உந்தி யாவிக்...."

(மருத்துவத் தனிப் பாடல்)

Vaatham, pitham, kabam are the three important humors of human body. These three humors are present all over the body. Among three *Vaatham* are more predominant in below the umbilicus, *Pitham* in abdomen and thorax, *kabam* are predominant in head and neck region.

GENERAL CHARACTERS OF VATHA DISEASES

"வாதம் வந்துற்ற போது வயிறது பொருமிக் கொள்ளும் தாதவிழ்ந்திடுப்பு கைகால் சந்துகள் கடுப்பு தோன்றும் சீதொரு மலமு நீருந் சிறுத்துடன் கடுத்து விழ மாதவமரை மேல் வந்த வாதத்தின் குணமிதாமே."

- Yugi Munivar Perunool Kaaviyam

Based on the text *Yugi Munivar Perunool Kaaviyam Vaatha* diseases are characterized by pain and swelling in joints, abdominal distension, constipation and burning micturition.

"காணப்பா வாதமீறில் கால்கைகள் பொருத்து நோவும் யணப்பா குடல் புரட்டும் மலசலம் பொருமி கட்டும் ஊணப்பா குளிருங் காய்ச்சல் உடம்பெல்லாம் குத்து வாய்வு வீணப்பா குதமிறுக்கும் வியர்வையும் வேர்க்கும் தானே."

- Agathiyar Vaithiya Kaaviyam -1500

Joint pain, nausea, constipation, oliguria, fever, rigor and sweating are produced due to vitiated vaatham.

IN THAERAYAR VAAGADAM:

"வாதவீறு அன்னமிறங்காது கடுப்புண்டாம் வண்ணமுண்டாம் மோதுகட்டு ரொகம் சுரமுண்டா மிருமலுமா முறங்காதேன்றும் ஓது சூரிய வாத மனலாகு நடுக்க முண்டாம் போருள்களாய்த் தீதனவே நரம்பிசித்து சந்துகள் தோறுங் கடுக்கும் தினமுந்தானே''

- Thaerayar Vaagadam

According to the *Thaerayar Vaagadam*, Loss of appetite, pain and redness, fever, cough, insomnia, shivering, pain in all joints is the characteristic features of vaatha diseases, which are mentioned in above text.

PROPERTIES OF VAATHAM:

"ஒழுங்குடனே தாதேழ் மூச்சோங்கி இயங்க எழுச்சிபெற எப்பணியுமாற்ற -எழுந்திரிய வேகம் புலன்களுக்கு மேவச் சுறுசுறுப்பு வாகளிக்கும் மாந்தர்க்கு வாயு"

- ம.த.பா

The following are the natural properties of Vaatham.

- 1. To stimulate
- 2. Respiration
- 3. To activate the Body, Mind and the Intellect.
- 4. To expel the fourteen different kinds of natural reflexes.
- 5. To activate the seven physical constituents in functional co-ordination.
- 6. To strengthen the five sense organs.

In the above processes Vaatham plays a vital role to assist the body functions.

Dearanged vaatham causes the following symptoms

- 1. Body ache and pain,
- 2. Pricking pain,
- 3. The pain as though the body is tightly bounded by cords,
- 4. Nervous debility,
- 5. Tremor,
- 6. Rigidness,
- 7. Dryness
- 8. Debility (Emaciation),
- 9. Throbbing pain (restriction of movements),
- 10. Trauma,
- 11. Displacement of joint (dislocation of joint),
- 12. Weakness of functional organs and loss of functions,
- 13. Loss of sensation or perception of astringent taste only,
- 14. Constipation ,concentrated urination,
- 15. Thirst,
- 16. Sensation of fragility in the foreleg and thigh,
- 17. Numbness and pricking pain in the bones,
- 18. Goose skin,
- 19. Stiffness of upper and lower limbs and back,
- 20. The skin, eyes, faeces and the urine are the black in colour.

CLINICAL FEATURES:

According to Yugi Vaithiya Chinthamani the following clinical features were seen:

- Stiffness of the body
- Sweating, body pain
- Paleness of the body
- Yellowish discolouration of stools and urine.

KINDS OF VAATHAM:

முறைமையாம் பிராணனோடபானன் வியானன் மூர்க்கமா முதானனொடு சமான னாகன் திறமையாங் கூர்மனோடு கிருக ரன்றான் தேவதத்த னொடுதனஞ்சயனு மாகும் –

(யுகிமுனி சிந்தாமணி 800)

Even though the vaatham seems to be the same, it has got ten different forms and actions.

TEN DIFFERENT KINDS OF VATHAM:

Praanan	-Air of life
Abaanan	-Air with downward motion (Flatus Air)
Viyaanan	-Air which spreads throughout
Udhaanan	-Air with upward motion
Samaanan	-Air with upward and downward motion
Naagam	-Air of higher intellectual function
Koorman	-Air of yawning
Kirukaran	-Air of salivation
Devathatthan	-Air of laziness
Dhananjayan	-Air that acts on death

SIDDHA PATHOPHYSIOLOGY:

Changes in lifestyle, occupation, food and other habits lead to development of this disease by causing derangement of muththaathus. Improper food habits alter the elemental composition directly while the other causes lead to derangement of these elements indirectly. When the elemental composition is altered, the uyir thaathukkal or the three humours which are made up of these elements naturally also get deranged. This simultaneously leads to derangement of seven udal thaathukkal, which produces symptoms of the disease 'Kuthikaal vatham'.

DIAGNOSIS

Diagnosis of 'Kuthikaal vaatham' in Siddha is based on Envagai thervugal and also on the other factors like

- 1. Uyirthaathukkal
- 2. Udalthaathukkal

- 3. Gnanenthiriyam
- 4. Kanmenthiriyam

ENVAGAI THERVUGAL:

It is a unique diagnostic method of siddha medical system. They are,

"நாடிப்பரிசம் நாநிறம் மொழிவிழி மலம் மூத்திரமிவை மருத்துவராயுதம்" "மெய்க்குறி நிறந்தொனி விழிநாவிருமலம் கைக்குறி" -தேரையர்

1. NAADI: (PULSE)

In kuthikaal vaatham, the following types of Naadi could be felt. They are Vathapitham, Pithavaatham, vathakabam, Kabavatham.

- **2. Sparism** Test sensation, temperature and nature of the skin
- **3.** Naa Test theColour of saliva, colour of sputum and nature of speech.
- **4.** Niram Test the Variation in pigmentation of skin.
- 5. Mozhi
- Vatham (Normal voice)
- Pitham (High pitched voice)
- Kabam (Low pitched voice)
- Thontham (Mixed all the above)

6. Vizhi

- Vatham (Black in colour, increased lacrimation))
- Pitham (Yellow or red in colour)
- Kabam (White in colour)
- 7. Malam Vatham (Stools are black in colour and constipated)
 - Pitham (Yellowish white in colour)
 - Kabam (White in colour)
 - Thontham (Mixed colour)

8. Moothiram

Collection of urine for the determination of Neerkkuri and Neikkuri, is an important diagnostic method **Neerkkuri**

Prior to the day of urine examination the patient is instructed to take a balanced diet. The patient should have good sleep. After waking up in the morning, the first urine voided is collected in a clear wide mouthed glass container and is subjected to analysis of "Neerkkuri" within one and a half an hour.

• Neikkuri

The collected specimen (Urine) is kept open in a glass dish or china clay container. It is to be examined under direct sunlight, without any shaking of the vessel.

Then add one drop of gingelly oil without disturbing the urinary specimen and the Neikkuri was noted in direct sunlight and conclude the diagnosis as follows,

Character of Vaathaneer

"அரவென நீண்டினஃதே வாதம்"

When the oil drop lengthens like a snake, it is called "VaathaNeer"

Character of Pithaneer

"ஆழி போற்பரவின் அஃதே பித்தம்"

When the oil drop spreads like a ring, it is called "Pitha neer

Character of Kabaneer

"முத்தொத்து நிற்கின் மொழிவதென் கபமே"

When the oil drop appears like a pearl, it is called "Kaba neer"

Character of Thonthaneer

"அரவிலாழியும் ஆழியில் அரவும்

அரவின் முத்தும் ஆழியில் முத்தும்

தோயிற்றில் தொந்த தோடங்களாமே"

Snake in the ring, ring in the snake, snake in the pearl and ring in the pearl are the characters of *Thontha neer*.

THREE UYIR THAATHUKKAL

1. Vaatham

In **Kuthikaal vaatham** patients among the ten types of vaatham; the following types are affected and causing symptoms accordingly.

1. Abaanan - Affected (causing constipation)

- 2. Viyaanan Affected (producing pain, restriction of joint movements)
- 3. Samaanan Affected (deranging the other four types of vatham)
- 4. Devathathan Affected (causing sleep disturbance)

2. Pitham

Among the Five types of pitham (Analaagam, Ranjagam, Pirasagam, Alosagam and Saathagam) the Saathaga pitham only affected in Kuthikaal vaatham patients and causing difficulty in walking, standing, difficulty in walking after getting up from bed in the morning.

3. Kabam

In the five types of Kabam (Avalambagam, Kilethagam, Pothagam, Tharpagam and Santhigam) avalambagam and Santhigam only affected in Kuthikaal vaatham patients and causing pain in heel region and restriction of movements in the both heel and ankle region.

SEVEN UDAL THAATHUKKAL:

Among the seven Udal Thaathukkal (Saaram, Senneer, Oon, Kozhuppu, Enbu, Moolai and Chukkilam/Suronitham) the following four are commonly affected in Kuthikaal vaatham patients.

- 1. Saaram Tiredness and weakness
- 2. Oon- Plantar fascia weakness
- 3. Kozhuppu Pain in heel region, restriction of movements.
- 4. Enbu Weakness of bone

GNANENTHIRIYAM

The Kuthikaal Vaatham patients are having the clinical features of pain and tenderness especially in heel region. These are felt through Mei.

KANMENTHIRIYAM

In Kuthikaal Vaatham patients, Kaal is affected. This is due to pain, difficulty in walking etc. Eruvai affected – difficulty in passing stools.

NOI KANIPPU VIVATHAM (DIFFERENTIAL DIAGNOSIS)

Some types of Vaatha diseases are mimicking like Kuthikal vaatham. Careful and clear history taking and examination will reveal the correct diagnosis. They are:

- A. Vaathathambam
- B. Vaathakarshanam

A. VAATHASTHAMBAM:

உற்பவிக்கும் வாதமது எழுந்து பொங்கி உயர்காலின் புறவடியைக் குடைந்து பற்றி தெற்பவிக்கும் வீக்கமாய்ச் செழும்ப லுண்டாய்த் தேகமெங்கு நோவாகித் திமிரு மாகி விற்பவிக்கும் வில்லுபோல் விதன மாகி மிடுக்கான மாந்தனைப்போல் விதன மாகிப் பற்பவிக்கும் பரன்றனையே நினையா மூடர் படுகின்ற வாதஸ்தம் பமுமாம் பாரே

-யூகிமுனி

- Pain in sole region
- Burning sensation
- Oedema
- General body tiredness
- Stiffness
- Opisthotonus condition

Even though pain in the sole region is mentioned here, the other symptoms are not relevant to kuthikaal vaatham. So I differentiate kuthikaal vaatham from vaathasthambam.

B. VAATHAKARSANAM:

பார்க்கின்ற வாதவுள் ளடியிற் சாணி பதித்துவைத் ததுபோலப் பாத மெங்கும் நோக்கின்ற குதினரம்புக் கால்க ளெங்கும் கொடிதான பாரமாய்த் திமிர்ப் புண்டாகி வார்க்கின்ற வார்த்தைகள் மிகவே செய்து வளைந்திடினு நிமிர்ந்திடினும் வசங்கொ டாமல் ஏர்க்கின்ற காலுளைக்கும் வாத கர்ஷணம் ஈதலற மில்லாதார்க் கெய்துங் காணே

-யூகிமுனி

- Feeling of dung like substance applied in the soles.
- Pain in heel region
- Heaviness
- Stiffness
- Difficulty in forward bending posture

Even though pain in the heel region is mentioned here, the other symptoms are not relevant to kuthikaal vaatham. So I differentiate kuthikaal vaatham from vaathakarsanam.

LINE OF TREATMENT

In Siddha system, the treatment is based on mukkutram theory. The line of treatment plays an important role in the normalization of mukkutram. Treatment is not only for curing the disease but also for the prevention recurrence of the symptoms and rejuvenation of udalkattugal. These are

- 1) Kaappu(Prevention)
- 2) Neekkam(Treatment)
- 3) Niraivu(Restoration)

Kaappu (Prevention)

The prevention of diseases were well said in the Siddha system of Medicine as mentioned in the text '**Theraiyar Pinianugaa Vithi**'

'பாலுண்போம் எண்ணெய்பெறின் வெந்நீர் குளிப்போம் பகற்புணரோம்; பகற்றுயில்வோம்: பாயோதரமு மூத்த

ஏலஞ்சேர் குழலியரோ டிளவெயிலும் விரும்போம்;

- ரண்டடக்கோம்; ஒன்ரைவிடோம்; - டதுகையிற் படுப்போம்'

The preventive methods for kuthikaal vaatham are;

- Control the body weight by diet and exercise
- > Avoid excessive intake of salty, sour, tinned food items.
- > Modify the nature of work which gives stress to a heel region.
- > Avoid prolonged standing and long distance walking.

NEEKKAM (TREATMENT)

In Siddha Maruthuvanga Churukkam, the deranged Vaatha can be balanced by purgation hence to start with.....

"விரேசனத்தால் வாதந் தாழும்"

Followed by usage of Internal and external drugs.

On first day: - Purgation:

Meganatha kuligai -2 with hot water early morning in empty stomach.

Internal drug:

Akkini Chooranam – 1.5 grams, twice a day.

External drug:

Veera Mezhugu – Q.S is given for external application over the affected area.

NIRAIVU (RESTORATION)

The diet should be normalizes the Vaatha and also strengthen the body.

DIETARY REGIMENS:

Avoid:

- Tubers except karunai kizhangu(Colocasia antiquorum)
- Maaporulghal(Carbohydrates)
- Vaazhaikkai (Musa paradisiaca)
- Kaaramani (Vigna unguiculata)
- Verkkadalai (Arachis hypogea)
- Pattaani (Pisum sativum)
- Mochai (Lablab purpureus)
- Kezhvaragu (Eleusine coracana)
- Kambu (Pennisetum typhoideum)
- Solum (Sorghum vulgare)
- Sour, astringent foods

During medication, should not sleep in day times, avoid sexual indulgence. Due to these activities excessive heat will be produced by sleep, sun heat, dietary regimen will causes the diseases.

MODERN ASPECT

MODERN ASPECT PLANTAR FASCIA antomy of plantar fascia:

The plantar fascia is the investing fascial layer of the plantar aspect of the foot that originates from the os calcis and inserts through a complex network to the plantar forefoot. It is a tough, fibrous layer, composed histologically of both collagen and elastic fibers. The terms planar fascia and plantar aponeurosis are often used interchangeably, although strictly speaking only the central part of the plantar fasia is extensively aponeurotic. It is analogous to the plantar fascia of the hand. The plantar fascia is thick structure, and not only serves a supportive ad protective role, but is also intricately involved with the weight-bearing function of the foot.

It is divided into three major areas.

- Central portion
- Medial portion
- Lateral section

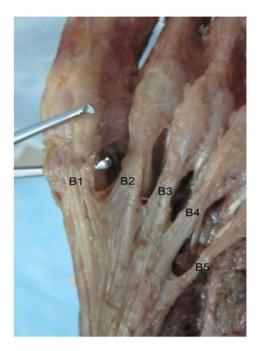
Central portion:

The central portion is the major portion of the plantar fascia both anatomically and functionally. This portion is the thickest and strongest and is narrowest proximally where it attachés to the medial process of the calcaneal tuberosity, proximal to the flexor digitorum brevis. This attachment site is often involved in a condition called plantar heel pain how ever, pain can occur anywhere along the structure. From its insertion, the central portion of the fascia fans out and becomes thinner distally. Its fibers are longitudinally oriented and adhere to the underlying flexor digitorum brevis muscle. The central portion envelops the flexor digitorum brevis muscle on both the sides, forming the medial and lateral inter muscular septums, which anchor the plantar fascia to the deep plantar pedis. At the mid shaft of the second to fifth MTP joint, the body of the central portion branches into five superficial longitudinal tracts. All five superficial longitudinal tracts terminate by inserting into, and blending with, overlying subcutaneous tissue and skin. Due to the anatomical connections of the central portion, dorsiflexion of the toe slides the plantar pads distally placing tension on the plantar aponeurosis. The central portion of the fascia primarily functions as a dynamic stabilizer of the medial longitudinal arch during weight-bearing activities.

Lateral and medial portions:

The smaller and thinner lateral and medial portions are thin and cover the under surface of the abductor digiti minimi and abductor hallucis muscles, respectively.





CENTRAL, LATERAL AND MEDIAL PORTIONS OF THE PLANTAR FASCIA

PLANTAR FASCIITIS

Plantar heel pain is defined as, pain arising from the insertion of the plantar fascia, with or without heel spur and has been experienced by 10% of the population. The condition often referred to as plantar fasciitis, is an inflammatory process. This is an annoying and painful condition that limits function. There is pain and tenderness in the sole of the foot, mostly under the heel, with standing or walking. The condition usually comes on gradually, without any clear incident or injury but sometimes there is a history of sudden increase in sporting activity, or a change of footwear, sports shoes or running surface. There may be an associated tightness of the Achilles tendon.

The pain is often worse when first getting up in the morning, with typical hobbling downstairs, or when first getting up pain and stiffness. The pain can at times be very sharp, or it may change to a persistent back ground ache as the patient walks about. The condition can take 18-36 months or longer to resolve, but is generally self-limiting, given time.

Epidemiology:

A survey of US professional football, baseball, and basketball team physicians and trainers found that plantar fasciitis was among the 5 most common foot and ankle injuries observed in professional athletes. It is estimated that approximately 1million patient visits per year are due to plantar fasciitis. Plantar fasciitis accounts for about 10% of runner-related injuries and 11-15% of all foot symptoms requiring professional care. It is through to occur in 10% of the general population as well. It may present bilaterally in a third of cases.

ETIOLOGY OF PLANTAR HEEL PAIN

Etiology of plantar heel pain is poorly understood, although a number of factors have been proposed

• Obesity:

Obesity has been shown to occur in 40% of men and 90% of women with plantar heel pain. A body mass index greater than 30kg/m² increases the risk of developing plantar heel pain.

• Occupational:

There is an association between plantar heel pain and prolonged standing or walking ("policeman's heel"), or a sudden changes in the stresses placed upon the feet likening this condition to other repetitive stress disorders such as carpal tunnel syndrome and tennis elbow.

• Acute injury:

Although less common, plantar heel pain may be associated with n acute injury to the heel. Some people recall stepping on a pebble, or other hard object, before pain began ("stone bruise").

• Inflammatory spondyloarthropathies:

These disorders should be considered when multiple joints or areas are involved. Upto 16% of patients presenting with subcalcaneal pain will later be diagnosed with a systemic arthritic disorder.

• Calcaned stress fracture:

The history for calcaneal stress fractures usually involves a sudden increase in a running activity, such as that seen in a military recruit at boot camp or a reservist.

• Nerve entrapment

• Tumors

- Infections
- Neuropathy (diabetic, alcoholic)
- The fat-pad syndrome
- Night splinting
- Orthotics
- Heel cups/taping
- Stretching and strengthening
- Deep frictional massage
- Corticosteroid injection
- Shoe modification
- Casting

Types of the plantar fasciitis

• Insertional plantar fasciitis :

It is otherwise called the 'Heel pain syndrome'. Pain is felt at the medial calcaneal tubercle (point tenderness).

• Diffuse plantar fasciitis:

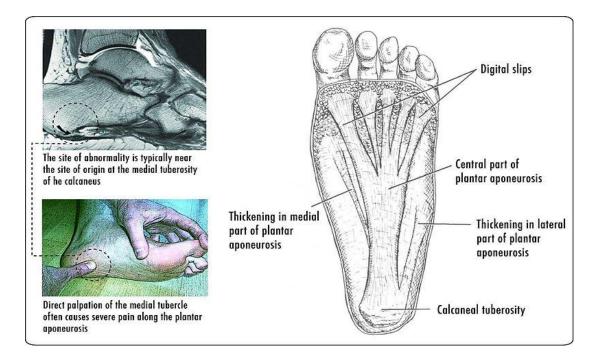
Pain felt diffusely over the heel and the sole of the foot.

PATHOLOGY:

Plantar fasciitis is an aseptic inflammation of the plantar fascia. The lesions affect the soft tissues at the site of attachment of the plantar aponeurosis to the inferior aspect of the tuberosity of the calcaneus. The spur is not a growth but a reaction to the local inflammation of the plantar fascia. The severity of the pain is not proportional to the size of the spur. Even big spurs may be asymptomatic and minimal spurs may be associated with severe pain.

PATHOMECHANISAM:

The functions of the plantar fascia are to support the medial longitudinal arch during static and dynamic loading of the foot, and to provide midfoot stability. It also assists the heel pad in dynamic shock absorption. Just after heel strike during the first half of the stance phase of the gait cycle, the tibia turns inward and the foot pronates to allow flattening of the foot. This stretches the plantar fascia. The flattening of the medial longitudinal arch allows the foot to accommodate the irregularities in the walking surface and also to absorb shock.



The plantar fascia functions throughout the windlass mechanism to limit the flattening of the foot and to elevate and stabilize the medial longitudinal arch. This occurs when the toes are dorsiflexed and passively pulling the plantar fascia under the metatarsal heads. Thus, each time the foot passes from heel rise to toe off in the stance phase of the gait cycle, the plantar fascia is placed under increased tension.

Mechanistically, hicks appears to be the first to describe the windlass mechanism by which passive dorsiflexion of the toes causes the medial longitudinal arch to rise, the hind foot to supine, the leg to externally rotate, and the plantar fascia to become more tense than when the foot an toes are in neutral. So that the plantar fascia act as a cable that is wound around the metatarsal head, which acts as a drum, with the proximal phalanx acting as a handle to provide the winding. The plantar fascia is prone to repetitive injury at the posterior insertion due to its role in maintain the medial longitudinal arch and through the stress placed on it by the shock absorbency function of heel. If there is a predisposing or aggravating factor, the repetitive traction placed on the plantar fascia during walking or running may lead to micro and macro tears, which induce a reparative inflammatory response. The heeling response is then interrupted by the continued stress produced by weight bearing, resulting in chronic degenerative changes.

Histological changes include collagen necrosis, angiofibroblastic hyperplasia, chondroid metaplasia and matrix clacification may occur. Pathologically, prolonged

inflammatory changes in the tissue are seen initially as edema, and are seen later as thickening of the plantar fascia.

CLINICAL FEATURES:

Pain in the heel, which is more in the morning. It gradually subsides as the patient takes a few steps. The pain increases on prolonged standing, walking, etc.

DIAGNOSTIC CRITERIA:

• Radiographs

Consisting of the routine Anterio posterior, lateral and oblique view is advised. However, the X-ray does not show any changes in plantar fasciitis. It helps to detect calcaneal spur and other heel pathologies.

• MRI

It can be helpful in excluding a calcaneal fracture, which is an important differential diagnosis.

DIFFERENTIAL DIAGNOSIS:

- The fat-pad syndrome
- Nerve entrapment
- Calcaneal fracture
- Inflammatory spondyloarthropathies
- Psoriatic arthritis
- Rheumatoid arthritis
- Trauma
- Tumor

MANAGEMENT:

- Rest
- Shoes with soft rubber pads
- Heat therapy

DRUG REVIEW

PROPRTIES OF TRIAL DRUGS

1. KODIVELI – Plumbago zeylanica, Linn.

Family : Plumbaginaceae

Useful part : Root

Organoleptic characters:

Taste	: Acrid
Potency	: Veppam
Division	: Acrid

Actions : Antipyretic

It is indicated for bodyache, vaatham and cancer.

Chemical constituents:

Two new quinines – Zeylanone, isozeylanone, plumbagic acid, plumbagin, bsitosterol, vanilic acid, steroidal glycoside.

Pharmacological activity:

- Anti-inflammatory, analgesic and antipyretic activity.
- Plumbagin inhibits LPS induced inflammation through the inactivation of nuclear factor-kappaB and mitogen activated protein kinase signalling pathway

(Food chem toxicol.2014 Feb; 64:177-83)

2. CHUKKU– Zingiber officinale, Rosc.

Family : Zingiberaceae

Useful part : Root tuber (dried)

Organoleptic Character:

Taste: Acrid

Potency : Veppam

Division : Acrid

Actions: Carminative, Stomachic

General properties:

Chukku is indicated for Vaatha diseases, sinusitis, headache.

வாதப் பிணிவயி றூதற் செவிவாய்

வலிதலை வலிசூலை வலியிரு விழிநீர்

சீதத் தொடுவரி பேதிப் பலரோ

சிகமலி முகமக முகமிடி கபமார்

- (தேரையர் குணவாகடம்)

Chemical constituents:

It is indicated for 1-2% volatile oil, resinous matter, diarylheptanoid, gingerol, gingerdione, starch, mucilage, sesquiterpenes like zingiberine, bisabolene.

Pharmacological activity:

Anti-inflammatory and Analgesic activity:

- Diarylheptanoid having catechol group showed activity against 5-Lox which further inhibited leukotriene biosynthesis which can produce anti-inflammatory effects.
- Gingerol and gingerdione showed analgesic and anti-inflammatory activity by inhibited the prostaglandin synthesis
 Stomachic, antioxidant, anti dote.

Indian Herbal Pharmacopoeia, P – 48

3. MILAGU – Piper nigrum.Linn

Family : Piperaceae

Useful part : Seeds

Organoleptic Character:

Taste: Bitter, acrid

Potency : Veppam

Division : Acrid

Actions: Antivaatha

General properties:

"சீதசுரம் பாண்டு சிலேத்மங் கிராணிகுன்மம் வாதம் அருசிபித்தம் மாமூலம்- ஓதுசன்னி யாசமபஸ் மாரம் அடன்மேகம் காசமிவை நாசங் கறிமிளகினால்."

- (அகத்தியர் குணவாகடம்)

Milagu is indicated for anaemia, dysentery, ulcer, fever, vaatha diseases, haemorrhoids.

Chemical constituents:

Oleoresin, alkaloid, volatile oil, alkaloid called piperine, amide known as pipericide.

Pharmacological activity:

Anti-inflammatory and Antipyretic activity:

- Piperine can effectively abrofath interleukin-1B induced over expression of inflammatory mediators.
- ✤ In humans piperine increases the bioavailability of antitubercular drugs.
- Piperin possesses CNS depressant, antipyretic,anti-inflammatory,antioxidant

-Indian Herbal Pharmacopoeia, P – 424

4. THIPPILI - Piper longum

- Family : Piperaceae
- **Useful part** : Fruit

Organoleptic Character:

Taste	: Sweet
Potency	: Veppam
Division	: Sweet

Actions : Carminative

General properties:

"வரும லப்பெருக் கோடு மகோதரம் வாதம் ஆதிமுத் தோடஞ் சுரங்குளளிர் பெருமாலைப்புரி மேகப் பிடகமும் பேருந் திப்பிலிப் பேரங்குரைக்கவே"

- (தேரையர் குணவாகடம்)

Uses :

Thippili is used for ascites, vaatham, pitham, kapham types of diseases, fever.

Chemical constituents:

Volatile oil, resin, alkaloids piperine, N-isobutyldecatrans-2-trans-4-dienamide, terpenoid substance, piperlongumine, piplartine.p-cymene.

Pharmacological activity:

Anti-inflammatory activity and Analgesic activity:

- Itt having anti-inflammatory and analgesic activity.
- Antiallergic, antiasthmatic ,hepatoprotective activity

Indian Herbal Pharmacopoeia, P – 315

• Piperine increases the bioavailability of chemotherapeutic drugs.piperine as a supplement to chemotherapeutic drugs to enhance their bioavailability.

(Herbal medicine: Acancer chemopreventive and therapeutic perspective-effects of natural polyphenols on chemoradiotherapy in cancer)

5. OMAM : Carum copticum

Family : Solanaceae

Useful part : Seeds

Organoleptic characters:

Taste	: Kaarppu
Potency	: Veppam
Division	: Kaarppu

General properties:

"சீதசுரங் காசஞ் செரியாமந் தம்பொருமல் பேதியிரைச் சல்கடுப்பு பேராமம்- ஓதிருமல் பல்லொடுபல் மூலம் பகமிவைநோ யென்செயுமோ? சொல்லொடு போம் ஓமமெனச் சொல்."

- (அகத்தியர் குணவாகடம்)

Chemical Constituents:

The chemical composition of essential oil obtained from dry dry fruits of carum. Thymol (35-60), a-pinene, p-cymene, limonene and a-terpinene have been found. Camphene, carvacrol, cvmene, dipentene, myrcne, phenols, terpinene, thymine, thymol, linoleic acid.

-Database, vol- VII, p-498

Actions:

Carminative, Stimulant, Stomachic, Anti spasmodic, Tonic, Antimicrobial, Diuretic, Antispasmodic.

Uses:

A paste of the curshed fruit is applied externally for relieving pains.

- Database, vol- VII, p-497-498

6. KADUGU: Brassica juncea

Family : Brassicaceae

Useful part : Seeds

Organoleptic characters:

Taste	: kaarppu
Potency	: veppam
Division	: kaarppu

General properties:

"இடிகாச நாசிசூ ரீளைகபம் பித்தங் கடி**வாத** சீதங் கடுப்போ-டுடலிற் படுகோட்டு நோயென்னும் பங்கிவைக ளைப்புண் கடுகோட்டு மேன்மருந்து காண்."

- (அகத்தியர் குணவாகடம்)

Chemical Constituents:

Glucosides – Sinalbin, sinargin, potassium myronate.

Actions:

Emetic, Stimulant, Rubefacients, Vesicant, Digestive, Diuretic.

Uses:

Powdered mustard mixed with hot water can be given for Hiccough, It is mixed with honey and can be given for Bronchial Asthma.

7. SIRUTHEKKU: Clerodendrum serratum (linn) Moon.

Family : Verbenaceae

Useful part : Leef, Root.

Organoleptic characters:

- Taste: Kaipu, Thuvarppu
- **Potency** : Veppam
- **Division** : kaarppu

General properties:

"கண்டுபா ரங்கியெனுஞ் சிறுதேக குண்டேல்,

காலெங்கே பித்தமெங்கே கபந்தா னெங்கே தொண்டுதொட்டுத் தொடர்சுவாச காச மெங்கே சுரமெங்கே வெறியெங்கே தொனிநோ யெங்கே''

- (தேரையர் குணவாகடம்)

Uses:

Siruthekku is used for body pain, fever, vaatha disease, asthma, sinusitis.

ACTIONS:

Stimulant, Sedative

Chemical constituents:

Flavonoids, glycosides, saponins, sterols, D-mannitol, sitosterol

Pharmacological activity:

Analgesic, anti-inflammatory, antifungal, antibacterial, antiprotozoal, anticancer and diuretic activities.

8. YAANAITHIPPILI: Scindapsus officinalis, Schott

Family :	Araceae
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Useful parts : Seeds

Organoleptic characters:

Taste	: kaarppu
Potency	: veppam
Division	: kaarppu

Action:

Stomachic, Stimulant, Anthelmintic, Sudorific (diaphoretic)

General Properties:

மாதமறுந் தீபனமா மாறாக் கபங்கரப்பான் ஒதுகுரற் கம்மலியை யோடுங்காண்-பூதலத்திற் சோனையைநேர் நாசினீர் தோலாச்சு வாசமும்போம் யானையினற் றிப்பிலிய தால்.

- (அகத்தியர் குணவாகடம்)

Uses:

It is used for cough, asthma, throat pain, abdominal discomfort.

9. KOSTAM: Costus speciosus, (Koenig x Retz.)

Family	: Zingiberaceae
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Useful parts : Root tuber

Organoleptic characters:

Taste	: Kaippu, V	Viruviruppu.
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Potency	: Veppam
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Division : Kaarppu

Actions:

Anti- inflammatory, Spasmolytic, Muscle relaxant, Tonic, Stimulant.

General properties:

"நாட்டிலுறு வெட்டை நடுக்கம் எனுநோய்கள் கோட்ட்மெனச் சொன்னால் குலையுங்காண்-கூட்டிற் சுரதோடந் தொண்டைநோய் தோலாத பித்தம் பரதேசம் போமே பறந்து."

- (அகத்தியர் குணவாகடம்)

Uses:

It is indicated for fever, throat disorders and pitha diseases.

Chemical constituents:

Rhizomes contains 2-4% Diosgenin. Rhizomes source of corticosteroids, sexhormones.

Pharmacological activity:

Anti-inflammatory, spasmolytic, antivenom, anthelmintic, analgesic, antipyretic effects, anticancer activities.

10. PERUNGAYAM: Ferula asafoetida

Family : Umbelliferaceae

Useful parts : Gum-Resins

Organoleptic characters:

- Taste: Kaippu, Karakarappu.
- **Potency** : Veppam
- **Division** : Kaarppu

General properties:

"தந்தவே தந்த மூலத்தெழும்பிணி சருவகாள்ம் விருச்சிகங்கீடம்மா மந்தம்**வாதம்** உதாவர்த்தம் அல்குல்நோய் மார்பணங்கட்ட குன்மம்மகோதரம்"

- (தேரையர் குணவாகடம்)

It is used for Gum diseases, snake poisons, scorpion poisons, vaatha diseases, ulcer, ascities.

Chemical constituents:

Organic sulphur compound, volatile oil containing essential oil of glicallyl,allylpersulphide and two terpenes, ferulic acid, ester of ssaresino- tannol, alsomail, acetic, formic and valerainic acids.

Actions:

Stimulant, Carminative, Anti spasmodic, Anthelmintic, Emmengagogue, Expectorant, Nervine tonic.

-Indian Medicinal plants vol-III orients Longaman, P-13.

11. VASAMBU: Acorus calamus

Useful parts : Rhizome

Organoleptic characters:

Taste	: Karppu.
Potency	: Veppam
Division	: Kaarppu

Actions:

Anodyne, Aphrodisiac, Aromaic, Febrifuge, sedative, Stimulant.

General properties:

"பாம்பதி நஞ்சற் புதப்புண் வலிவிடபாகங் குன்மம் சூம்பா ரிரத்தபித் தம்முக நாற்றம்வன் சூலைசன்னி வீம்பாம்பை காசம் பிலீகஞ் சிலிபதம் வீறிருமல் தாம்பாங் கிருமி யிவையேகு மாசிவ சம்பினையே.

- (தேரையர் குணவாகடம்)

Chemical constituents:

Asarone, Calamenol, Calamene, Eugenol, Methyl, Eufenol, Pinene, Camphene, Calamol, Azulene.

Database Vol- I, p-471

Action:

Stimulant, Stomachic, Antiperiodic Carminative, Nauseant, Emetic, Disinfectant, Germicide, Spasmolytic, Hypothermic, Anticonvulsant

-Database Vol-I, P-471

Uses:

Plant causes sedative effect. It also reduces pain (Analgesic effect)

Phytochemicals:

Glucoside acorin renders the aromatic. Acorenone, isoshyobunine, b-asarone, calamendiol, -selinene, a-calacorene, calamuseneone, camphone and shyobunone are the constituents of the essential oil of sweet flag.

12. SOTRUPPU- Sodium chlorid

Taste	: Uvarppu
Potency	: Veppam.
Division	: Kaarppu.

General properties:

"அளத்திலுறை நல்லுப் பனல்வாதம் மற்றுங் களத்துநோய் தன்னைக் களையுங்-கிளைத்தகப ஆசுடைய வல்லைநோய் அஷ்டகுன்ம மும்போக்குங் காசினியுள் மாதே கழறு"

Actions:

Stomachic, Laxative, Emetic, Anthelmintic, Antiperiodic.

13. INDHUPPU- Sodium Chloride Impura

Taste	: Uvarppu
Potency	: Veppam.
Division	: Kaarppu.

General properties:

"அட்டகுன்ம மந்தம் அசிர்கரஞ்சூர் சீதபித்தந் துட்டவையம் நாடிப்புண் டோடங்கள்-கெட்டமலக் கட்டுவிட விந்தையக் காமியனோய் வன்கரப்பான் விட்டுவிட விந்துப்பை விள்"

Actions: Stomachic, Diuretic, Carminative.

14. SARKARAI- Saccharum ofificinarum.Linn

Family : Gramineae

Useful parts : Root and stem juice

Organoleptic Characters:

Taste	: Sweet
Potency	: Seetham

Division : Sweet

Actions:

Cooling, antiseptic, diuretic, nutrient, demulcent

General properties:

"சீனிச் சர்க்கரைக்குத் தீராத வன்சுரமுங் கூனிக்கும் **வாதத்தின்** கூட்டுரறவும்-ஏனிற்கும் வாந்தி யொடுகிருமி மாறாத விக்கலுமே போந்திசையை விட்டுப் புரண்டு"

- (அகத்தியர் குணவாகடம்)

It is used for **vaatha** disease, fever, vomiting, hiccough.

PROPERTIES OF EXTERNAL MEDIINE

1. VEERAM- HYDRAGYRUM PERCHLORIDE

Taste : Bitter

Potency : Veppam.

Division : Kaarppu.

Actions: Tonic, Antiseptic and Caustic properties.

General properties:

''குன்மமொடு குட்டங் கொடியவனி லத்திரட்டு

துன்மாங் கிசப்பெருக்கஞ் சூலைநோய்-வன்மையுறு

காமியப்புண் ணாதியநோய் கண்டாற்சவ்

வீரனெனுஞ் சாமிநா மத்தையுச் சரி"

Uses : Gastric ulcer, leprosy, severe **vatha diseases** and morbid growth of flesh, throbbing pain, venereal disease, eye diseases

2. HONEY WAX

Action : Demulcent

Uses : Ointment, creams, paste, plaster.

General properties:

"அறைபக்க **வாத** மதைப்பைய மூதை குறைவிந்தி தழ்நோய் தேள்கூளி-கறையைப் புழுகெடுக்க வங்கமுறு புண்ணிடிபுண் டீப்புண் மெமுகெடுக்க வாங்கலு மெய்"

Uses : Vaatha disease, edema, hemiplegia, scorpion poison, leprosy, wounds.

3. COCUNUT OIL: Cocos nucifera

Family : Arecacea

Useful parts : Endosperm

Organoleptic Characters:

Potency : Thatpam

Division : Sweet

Actions: Refrigerant, nutrition, demulcent,

General properties:

"தேங்காயி னெய்யதனாற் ரியால் வருபுண்போம்

பாங்காகக் கூந்தற் படர்ந்தேறு-நீங்காத

பல்லடியின் னோயும் படர்தா மரைசிரங்கும்

அல்லறப் போமென் றறி"

- (அகத்தியர் குணவாகடம்)

Chemical Constituents:

Amino acids-Arginine, alanine, lysine, histidine, tyrosine,

Fatty acids-Lauric acid, myristic acid.

INGREDIENTS OF AKKINI CHOORANAM

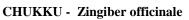
THIPPILI - Piper longam



INDHUPPU-ROCK SALT



KODIVELIVER - Plumbago zeylanica





MILAGU - Piper nigrum



KOSTAM - Costus speciosus





VASAMBU- Acorus calamus

KADUGU- Brassica junceae





OOMAM - Carum copticum

YAANAI THIPPILI - Scindapsus officinalis



PERUNGAYAM - Ferula asafoetida





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SOTTRUPPU- SODIUM CHLORIDE

SUGAR- Saccharum officinarum





INGREDIENTS OF VEERA MEZHUGU

VEERUM- HYDRAGYRUM PERCHLORIDE



THEAN MEZHUGU- HONEY WAX



COCONUT OIL - Cocus nucifera



MATERIALS AND METHODS

MATERIALS AND METHODS

STANDARD OPERATIVE PROCEDURE

Source of Trial Medicine:

The required raw drugs for the preparation of *Akkini Chooranam* (Internal) and *Veera Mezhugu* (External) will be purchased from a well reputed country shop and the raw drugs will be authenticated by the competent authority. After that the raw drugs will be purified separately and the Medicine is prepared in Gunapadam laboratory - National Institute of Siddha.

The herbal ingredients of the trial drug get authendicated from Dr.D.Aravind, Assisant Professor, Department of Medicinal Botany, National Institute of Siddha, Chennai. The Mineral ingredients get authenticated from Siddha Central Research Institute, Chennai.

PREPARATION OF TRIAL DRUGS:

A. Internal Medicine:

Ingredients:

-	1 Palam (35 gms)
-	1Palam (35 gms)
-	1 Palam (35 gms)
-	1 Palam (35 gms)
-	1 Palam (35 gms)
-	1 Palam (35gms)
-	1 Palam (35 gms)
-	1 Palam (35 gms)
-	¹ / ₄ Palam(8.75gms)
-	¹ / ₄ Palam(8.75gms)
-	¹ / ₂ Palam(17.5gms)
-	9Palam(315 gms)

Purification of Raw Drugs:

Kodiveli:

Inner nerve of the root is removed, then the outer part is dried and make into powder. The powder is taken in a broad mouthed vessel containing cow's milk, closed with another broad mouthed vessel, subjected to heat for three hours. Finally the product is finely powdered in a Kalvam and taken.

Chukku:

Soak in lime stone water for 1 Saamam (3 hours) and dry it in shade then peel off the outer layer.

Milagu:

Soak in butter milk for 1 Saamam (3 hours) then allow it to dry.

Thippili:

Soak in juice of Lime for a period of time then allow it to dry.

Omam:

Soak in lime stone water then dry it.

Siruthekku:

Outer layer is peeled off made into small pieces then dried in sunlight.

Yaanai Thippili:

Soak in kaadi for a period of 1 saamam (3 hours) then dry it in sunlight.

Kostum:

Remove Unwanted dust and stones dry it in sunlight.

Sottruppu:

Soak in butter milk and then dry it in sunlight.

Indhuppu:

Soak in kaadi for a period of 3days then dry it in sunlight.

Perungayam:

Fried in an mud vessel.

Vasambu:

Exposed to flame until it becomes coal.

Kadugu:

Remove unwanted dust and stones, dry it for 2 days in sunlight.

Method of preparation:

The purified *Kodiveli*, *Thirikadugu*, *Omam*, *Sirutheku*, *Yaanaithippili*, *Kostam* were fried still it becomes golden colour then they were powdered and sieved by a cloth. The *sottruppu* and *indhuppu* were made it into fine powder in a culvam. The the purified *Perungayam* and *Vasambu* were also powdered separately.

The above powders were mixed together along with *Kadugu* powder and equal amount of sugar is added to the total amount of all the above mentioned drugs and mixed thoroughly. Then it was stored in a clean container.

B. External Medicine:

Ingredients:

•	Veeram	(Hydragyrum	per chloride)	- 1Thola (12gram)
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- Then mezhugu (*Honey* wax) 1Palam (35gram)
- Thengai ennai (Coconut oil) Q.S.

Purification of drug:

Veeram:

Take *veeram* in a container and put cow's milk above the level of *veeram* fully merged and dry in a sun light.

Method of preparation:

First *veeram* should be powdered in a kalvam. Take a vessel and put honey wax on that, heated for sometimes after getting melted, above *veeram* powder and coconut oil should be mixed and make it into a paste and stored in a clean container.

Drug storage:

The trial drug *Akkini chooranam* is stored in clean and dry container and *Veera mezhugu* is stored in clean and dry bottles.

Dispensing:

The Chooranam is given in packets and Mezhugu is given in Ziplock covers.

TRIAL DRUGS

AKKINI CHOORANAM:



VEERA MEZHUGU:



CHEMICAL EVALUATION

Experimental procedure:

5gms of *Akkini Chooranam* was taken in a 250 ml of clean beaker and 50ml of distilled water was added to it. Then it was boiled well for about 10 min. Then it is allowed to cool and filtered in a 100 ml volumetric flask and made up to 100 ml with distilled water. This preparation is used for the qualitative analysis of acidic/ basic radicals and biochemical constituents in it.

Preparation of extract:

5gm of *Akkini Chooranam*is weighed accurately and placed in a 250ml clean beaker and 50ml of distilled water was added with it. Then it was boiled well for about 10 minutes. Then it was allowed to cool and filtered in a 100ml volumetric flask and made up to 100ml with distilled water. The chemical analysis of *Akkini Chooranam* was done at Biochemistry lab, National Institute of siddha, Chennai-47.

Preliminary test for Copper, Sodium, Silicate and Carbonate:

> Test for Silicate:

- a. A little (500mg) of the sample is shaken well with distilled water.
- b. A little (500mg) of the sample is shaken well with con. HCl/Con. H₂So₄.
- Action of Heat: A small amount (500mg) of the sample is taken in a dry test tube and heated gently at first and then strong.
- Action of Heat: A small amount (500mg) of the sample is taken in a dry test tube and heated gently at first and then strong.
- Flame Test: A small amount (500mg) of the sample is made into a paste with con. HCl in a watch glass and introduced into non-luminous part of the Bunsen flame.
- Ash Test: A filter paper is soaked into a mixture of sample and dil. cobalt nitrate solution and introduced into the Bunsen flame and ignited.

Test For Acid Radicals

- Test For Sulphate: 2ml of the above prepared extract was taken in a test tube and 2ml of 4% dil. ammonium oxalate solution was added.
- Test For Chloride: 2ml of the above prepared extracts was added with 2ml of dil-HNO₃ until the effervescence ceases off. Then 2 ml of silver nitrate solution was added.

- Test For Phosphate: 2ml of the extract was treated with 2ml of con.HNo3 and 2ml of dil. ammonium molybdate solution.
- Test For Carbonate: 2ml of the extract was treated with 2ml dil. magnesium sulphate solution
- Test For Nitrate: 1gm of the substance was heated with copper turning and concentrated H₂SO₄ and viewed the test tube vertically down.
- > Test For Sulphide: 1gm of the substance was treated with 2ml of con. HCL
- Test For Fluoride & Oxalate: 2ml of extract was added with 2ml of dil. Acetic acid and 2ml dil.calcium chloride solution and heated.
- Test For Nitrite: 3drops of the extract was placed on a filter paper, on that-2 drops of dil.acetic acid and 2 drops of dil. Benzidine solution were placed.

Test For Basic Radicals

- Test For Lead: 2ml of the extract was added with 2ml of dil. potassium iodine solution.
- Test For Copper: One pinch (50mg) of substance was made into paste with con. HCl in a watch glass and introduced into the non-luminous part of the flame.
- Test For Aluminium: In the 2ml of extract dil. sodium hydroxide was added in 5 drops to excess.
- > Test For Iron:
 - To the 2ml of extract add 2ml of dil. ammonium solution
 - To the 2ml of extract 2ml thiocyanate solution and 2ml of con HNo3 is added.
 - Test For Zinc: In 2ml of the extract dil.sodium hydroxide solution was added in 5 drops to excess and dil.ammonium chloride was added.
 - Test For Calcium: 2ml of the extract was added with 2ml of 4% dil.ammonium oxalate solution
 - Test For Magnesium: In 2ml of extract dil.sodium hydroxide solution was added in drops toexcess.
 - Test For Ammonium: In 2ml of extract 1 ml of Nessler's reagent and excess of dil. sodium hydroxide solution were added.
 - Test For Potassium: A pinch (25mg) of substance was treated with 2ml of dil. sodium nitrite solution and then treated with 2ml of dil. cobalt nitrate in 30% dil. glacial acetic acid.

- Test For Sodium: 2 pinches (50mg) of the substance was made into paste by using HCl and introduced into the blue flame of Bunsen burner.
- Test For Mercury: 2ml of the extract was treated with 2ml of dil. sodium hydroxide solution.
- Test For Arsenic: 2ml of the extract was treated with 2ml of dil. sodium hydroxide solution.

Other constituents

- > Test For Starch : 2ml of extract was treated with weak dil. iodine solution
- Test For Reducing Sugar: 5ml of Benedict's qualitative solution was taken in a test tube and allowed to boil for 2 minutes and added 8 to 10 drops of the extract and again boil it for 2 minutes.
- > Test For The Alkaloids:
 - 2ml of the extract is treated with 2ml of dil. potassium iodide solution.
 - 2ml of the extract is treated with 2ml of dil. picric acid.
 - Test For Tannic Acid: 2ml of extract was treated with 2ml of dil. ferric chloride solution
 - Test For Unsaturated Compound: In the 2ml of extract 2ml of dil. Potassium permanganate solution was added.
 - Test For Amino Acid: 2 drops of the extract was placed on a filter paper and dried well, and then 20ml of Burette reagent was added in it.

CLINICAL STUDY:

STUDY DESIGN:

An open clinical trial

STUDY PLACE:

Ayothidoss Pandithar Hospital, National Institute of Siddha, Tambaram sanatorium, Chennai-47.

STUDY PERIOD : 18 months

SAMPLE SIZE : 40 patients

SUBJECT SELECTION:

Patients reporting with symptoms of *Kuthikaal vaatham* will be subjected to screening using screening Proforma. Then they will be allowed for the study fulfilling the following criteria.

INCLUSION CRITERIA:

- Age : 20 60 Yrs
- Sex : Both male and female
- Pain and tenderness in the sole of the foot while on walking and standing.
- Heel Pain gets worse when getting up in the morning.
- Patients willing to undergo radiological investigation and Laboratory investigations.
- Patients willing to sign the informed consent.

EXCLUSION CRITERIA:

- H/o Cardiac diseases
- H/o Diabetes mellitus
- H/o Rheumatoid arthritis
- H/o Chronic kidney disease
- Pregnancy and lactation
- Septic arthritis
- Gonococcal arthritis
- Psoriatic arthritis
- Patient with any other serious systemic illness.

WITHDRAWAL CRITERIA:

- Intolerance to the drug and development of adverse reactions during drug trial.
- Poor patient compliance and defaulters.
- Patient turning unwilling to continue in the course of clinical trial.
- Occurrence of any serious illness

TESTS AND ASSESSMENTS:

- A. Clinical assessment
- B. Laboratory investigations
- C. Radiological investigations
- D. Siddha system assessment

A.CLINICAL ASSESSMENT:

- Pain
- Swelling
- Stiffness
- Tenderness
- Warmth
- Restricted movements.

B. Routine investigation:

Blood:

- Hb
- Total WBC Count
- DC- Polymorphs
 - 1. Lymphocytes
 - 2. Eosinophil
 - 3. Monocytes
 - 4. Basophils
- Total RBC count
- ESR

¹/₂ Hr: 1 Hr:

- Blood sugar
 - Fasting: PP:

Urine:

- Albumin
- Sugar
- Deposits

Renal function tests:

- Urea
- Creatinine

Liver function tests:

- Serum total bilirubin
- Direct bilirubin
- Indirect bilirubin
- Serum Alkaline phosphatases
- SGOT
- SGPT

C. SPECIFIC INVESTIGATIONS:

- CRP
- ASO TITRE
- RA FACTOR

D. RADIOLOGICAL INVESTIGATIONS

• X- Ray Heel (AP and Lat view)

E. SIDDHA PARAMETERS:

Envagai thervugal:

- Naadi
- Sparisam
- Naa
- Niram
- Mozhi
- Vizhi
- Malam
- Moothiram
 - Neerkkuri
 - Neikkuri

DATA COLLECTION FORMS:

Required information will be collected from each patient by using the following forms:

FORMS:

- Form I Screening and selection Proforma
- Form II History taking & Clinical assessment Proforma
- Form III_ Laboratory investigation Proforma

- Form IV Drug compliance form
- Form V Patient information sheet
- Form VI Consent form
- Form VII Withdrawal form
- Form VIII Dietary Advice form
- Form IX Pharmacovigilance form

STUDY ENROLLMENT:

Patients reporting at the OPD with the clinical symptoms of *Kuthikaal vaatham*, examined clinically for enrolling in the study based on the inclusion and exclusion criteria.

The patients who were enrolled would be informed (Form VI) about the study, trial drug, possible outcomes and the objectives of the study in the language and terms understandable to them and informed consent were obtained in writing from them in the consent form (Form VI). All these patients were given unique registration card in which patients Registration number of the study, Address, Phone number and Doctors phone number etc. were given to report easily for any complications arises.

Complete clinical history, complaints and duration, examination findings and laboratory investigations -- would be recorded in the prescribed Proforma. Patients were advised to take the trial drug and to follow the appropriate dietary advice.

CONDUCT OF THE STUDY:

Purgation with *Meganaatha Kuligai-2pills* with Hot water at early morning in empty stomach was given for balancing the deranged mukkutram a day before the treatment.

The trial drugs *Akkini chooranam* (Internal) and *Veera mezhugu* (External) given continuously for 48 days. Patients were requested to visit the hospital OPD once in seven days for this study. The severe cases (patients unable to walk) were admitted in the IPD and progress assessed daily. In every visit the clinical assessment done and prognosis noted in the Prescribed Proformas in the presence of Faculty members of Dept. of Sirappu Maruthuvam. Laboratory investigations and Radiological investigation was done before and last day of the trial. Defaulters were not allowed to continue and withdrawn from the study.

DATA ANALYSIS:

After enrolling the patient for the study, a separate file for each patient and all forms were kept in the file. Study No. and Patient No. were written on the top of file for easy identification. Whenever the patient visits OPD during the study period, the respective patient's file taken and necessary entries were made at the assessment form or other suitable form. The screening forms were filed separately. The data recordings were monitored for completion and adverse event by HOD and pharmacovigilance committee. All forms were further scrutinized in presence of Investigators by Sr. Research Officer (Statistics) for logical errors and incompleteness of data to avoid any bias.

ADVERSE EFFECT/SERIOUS EFFECT MANAGEMENT

If the trial patient develops any adverse reaction, he/she would be immediately withdrawn from the trial and proper management was given in OPD of National Institute of Siddha and the same informed to the Pharmaco-vigilance committee of NIS.

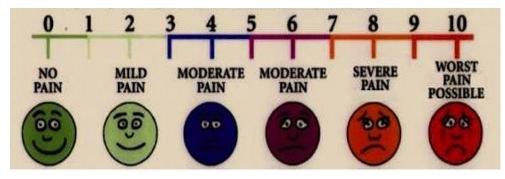
OUTCOME:

Primary outcome:

Primary outcome of the study is pain relieving and it will be assessed by the following methods:

- 1. Universal Pain assessment scale (before and after treatment)
- 2. Restricted movement assessment scale (before and after treatment)

1. UNIVERSAL PAIN ASSESMENT SCALE:



- Grade 0 : No Pain
- Grade 1-3 : Mild pain
- Grade 4-6 : Moderate pain
- Grade 7-10 : Severe pain

The improvement is assessed by pain scale method. They are

Grade 0	- Good Improvement
Grade 1-3	- Moderate Improvement
Grade 4-6	- Mild Improvement
Grade 7-10	- No Improvement Improvement

2. RESTRICTED MOVEMENT ASSESSMENT SCALE: GRADATION OF MOVEMENTS

GRADE 1 • THE TOT ALL ACTIVITIES. CALL OF THE WORK WITHOUT SUPPOR	GRADE I	- Fit for all activities. Can do their work without support
--------------------------------------------------------------------------	----------------	-------------------------------------------------------------

GRADE II - Mild restriction of movements, Mild pain present in Heel.

GRAD III - Moderate restriction of movements, Stiffness, Pain in Heel

GRADE IV - Bed ridden/ confined to chair, Severe pain.

(Communication-technology society. http://pectlab dev.spcomm.uiuc.edu/drupal/ (submitted by DIMO 17 on wed, 03/09/2011)

OBSERVATION AND RESULTS

RESULTS OF CHEMICAL ANALYSIS QUALITATIVE ANALYSIS

PHYSICO-CHEMICAL ANALYSIS

Table-1: Colour, nature of Akkini Chooranam

S.no	Parameters	Results	Method of Testing
1.	Colour	Brown	By visual
2.	Odour	Odour(Omam Smell)	Olfactory examination
3.	Solublity	Soluble in honeySoluble in water	Qualitative
4.	Nature	Powder	By visual

Table-2: Test for Basic radicals

S.no	Procedures	Akkini Chooranam
1.	Test for Ammonium	
2.	Test for Sodium	-
3.	Test for Magnesium	-
4.	Test for Aluminium	-
5.	Test for Potassium	+
6.	Test for Calcium	+
7.	Test for Ferrous iron	+
8.	Test for Copper	_
9.	Test for Zinc	_
10.	Test for Arsenic	-
11.	Test for Mercury	-
12.	Test for Lead	-

Inference

Bio-chemical analysis for basic radicals reveals that Akkini Chooranam contains Potassium, Calcium and Iron.

Table-3: Test for Acidic radicals

S.no	Procedures	Akkini Chooranam
1.	Test for Sulphate	+
2.	Test for Chloride	+
3.	Test for Phosphate	+
4.	Test for	
	Flouride&Oxalate	-
5.	Test for Nitrate	-

Table-4: Test for Acidic radicals

S.no	Procedures	Akkini Chooranam
1.	Test for Starch	+
2.	Test for Reducing sugar	+
3.	Test for Alkaloids	+
4.	Test for Amino acids	-
5.	Test for Tannic acids	+
6.	Test for type of compounds	No Change

Inference

Bio-chemical analysis for acid radicals reveals that Akkini Chooranam contains Sulphate, Chloride, Starch, reducing sugar, Alkaloids, Tannic acids

CLINICAL STUDY

OBSERVATIONS AND RESULTS

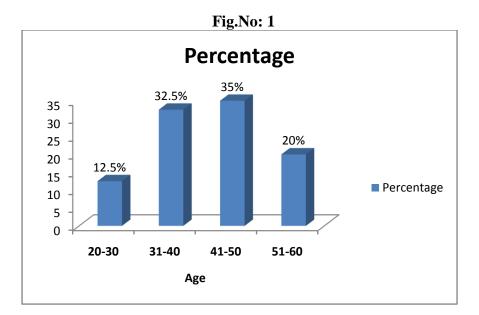
Results and observations were studied and tabulated under the following heading.

- 1. Age distribution
- 2. Sex distribution
- 3. Occupational status
- 4. Diet habits
- 5. Thinai reference
- 6. Paruva kaalam (Seasonal changes)
- 7. Socioeconomic status
- 8. Yakkai ilakkanam (Physical Constitution)
- 9. Gunam
- 10. Duration of illness
- 11. Clinical features
- 12. BMI
- 13. Distribution of Vaatham
- 14. Distribution of Pitham
- 15. Distribution of kabam
- 16. Udal Thaathukkal
- 17. Envagaithervu
- 18. Neikkuri
- 19. Outcome
- 20. Results

1. AGE INCIDENCE:

Table: 1. Distribution of age

AGE(YEARS)	NUMBERR OF CASES	PERCENTAGE
20-30	05	12.5 %
31-40	13	32.5%
41-50	14	35%
51-60	08	20%
TOTAL	40	100%



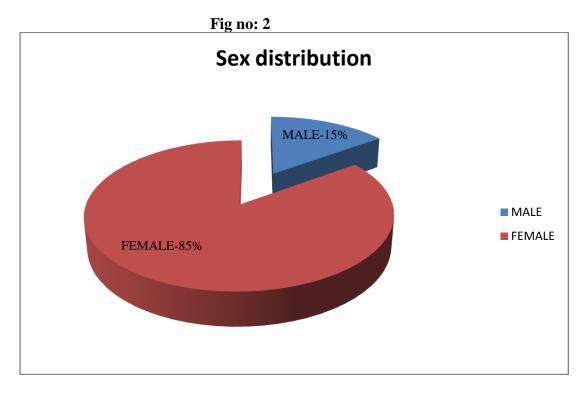
Observation

In my study, the incidence of disease is more in the Age group between 41-50 years of age.

2. SEX DISTRIBUTION

Table 2:

GENDER	NUMBER OF CASES	PERCENTAGE
MALE	6	15%
FEMALE	34	85%
TOTAL	40	100%



Observation

In this study among 40 patients Female was 85% and Male was 15%. Female was more affected than male was noted in my study.

3. OCCUPATIONAL DISTRIBUTION

Table 3:

OCCUPATION	NO. OF CASES	PERCENTAGE
House wife	16	40%
Teacher	2	5%
Coolie	10	25%
Security	2	5%
Clerical	10	25%
Total	40	100%

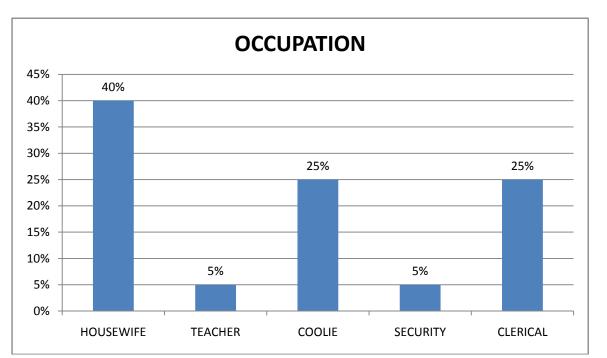


Fig no: 3

Observation:

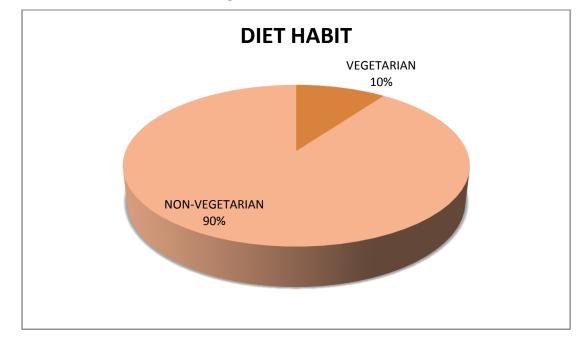
Among the 40 patients recruited, the prevalence were more in Housewives 16 (40%), 2 (5%) were in Teacher,10 (25%) were in Coolie , 2 (5%) in Security, 10 (25%) Were in clerical.

4. DIET HABIT

Table: 4

DIET HABIT	NUMBER OF CASES	PERCENTAGE
Vegetarian	4	10%
Non-Vegetarian	36	90%
Total	40	100%





Observation:

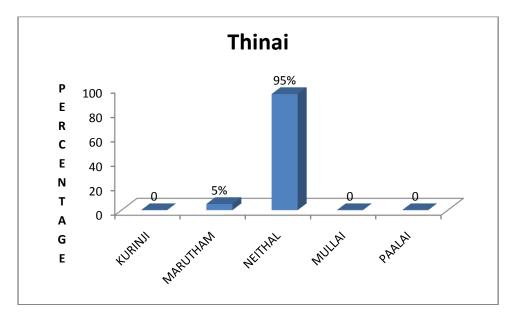
Among the 40 cases recruited, the prevalence of the disease seems to higher in Non vegetarian 36(90%) cases than in Vegetarian 4(10%) cases.

5. THINAI

Table: 5

THINAI	NUMBER OF CASES	PERCENTAGE
KURINJI	0	0%
MARUTHAM	2	5%
NEITHAL	36	95%
MULLAI	0	0%
PAALAI	0	0%
TOTAL	40	100%





Observation:

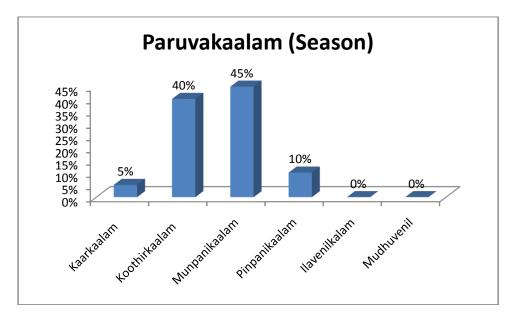
Among the 40 patients recruited, 38 (95%) cases belong to Neithal thinai, 2 (5%) cases belongs to Marutham.

6. PARUVA KAALAM (SEASON)

Table 6:

PARUVA KAALAM	NUMBER OF CASES	PERCENTAGE
Kaarkaalam (Aug 16 – Oct 15)	2	5%
Koothirkaalam (Oct 16 – Dec 15)	16	40%
Munpanikaalam (Dec 16 – Feb 15)	18	45%
Pinpanikaalam (Feb 16 – Apr 15)	4	10%
Ilavenilkalam (Apr 16 – Jun 15)	0	0%
Mudhuvenil (Jun 16 – August) 15)	0	0%
Total	40	100%





Observation:

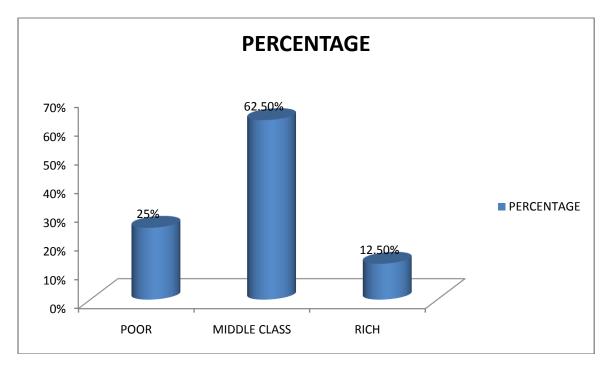
Among the 40 patients, 16 (40%) were recruited in koothir kaalam, 18 (45%) in munpanikalam, 2 (5%) in kaarkaalam & 4 (10%) cases in pinpani kaalam.

7. SOCIO-ECONOMIC STATUS

Table 7:

SOCIO-ECONOMIC STATUS	NUMBER OF CASES	PERCENTAGE
Poor	10	25%
Middle Class	25	62.5%
Rich	5	12.5%
Total	40	100%





Observation:

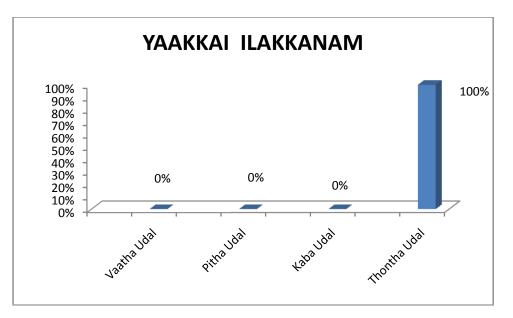
Among the 40 patients recruited, 25 (63%) cases belong to Middle class, 10 cases (25%) belong to Poor status and 5 (12.5%) cases belong to rich status.

8. YAAKKAI ILAKKANAM (PHYSICAL CONSTITUTION)

Table: 8

CONSTITUTION OF THE BODY	NUMBER OF CASES	PERCENTAGE
Vaatha Udal	0	0%
Pitha Udal	0	0%
Kaba Udal	0	0%
Thontha Udal	40	100%





Observation:

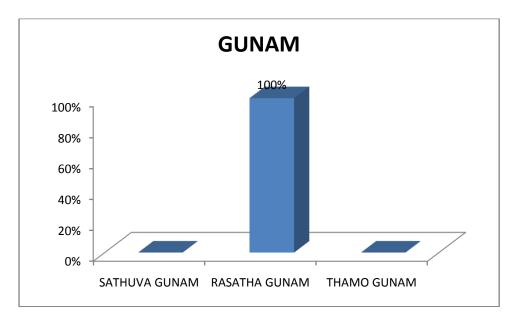
Among the 40 (100%) patients recruited, all of them were belongs to Thontha Udal.

9. GUNAM

Table 9

GUNAM	NUMBER OF CASES	PERCENTAGE
SATHUVA GUNAM	0	0%
RASATHA GUNAM	40	100%
THAMO GUNAM	0	0%
TOTAL	40	100%





Observation:

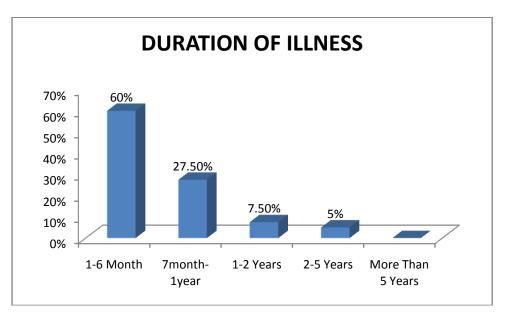
All the 40 patients were under Rasatha gunam.

10. DURATION OF ILLNESS:

Table: 10

DURATION OF ILLNESS	NO.OF CASES	PERCENTAGE
1-6 Month	24	60%
7month- 1year	11	27.5%
1-2 Years	3	7.5%
2-5 Years	2	5%
More Than 5 Years	0	0%





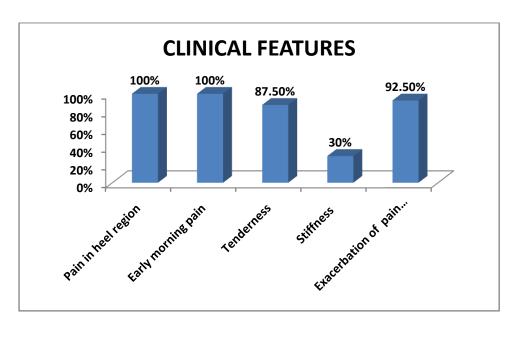
Observation:

Among the 40 patients, 60% of cases had 1-6 month of illness, 27.5% of cases had 7 months- 1 year, 7.5% of cases had 1-2 years, and 5% of cases had 2-5 years of illness.

11. CLINICAL FEATURES

Table 11

CLINICAL FEATURES	NUMBER OF	PERCENTAGE
	PATIENTS	%
Pain in heel region	40	100%
Early morning pain	40	100%
Tenderness	35	87.5%
Stiffness	12	30%
Exacerbation of pain on movements	37	92.5%





Observation:

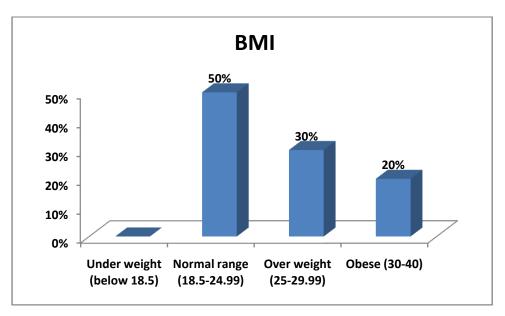
Among the 40 cases, all of them (100%) had Heel pain and early morning pain in heel region, 35 (87.5%) cases had diffuse tenderness with limitation of movements, 12 (30%) cases had stiffness and 37 (92.5%) cases had exacerbation of pain on movements.

12. BMI

TABLE No: 12

BMI	Number of Cases	Percentage
Under weight (below 18.5)	0	0%
Normal range (18.5-24.99)	20	50%
Over weight (25-29.99)	12	30%
Obese (30-40)	8	20%
Total	40	100%





OBSERVATIONS

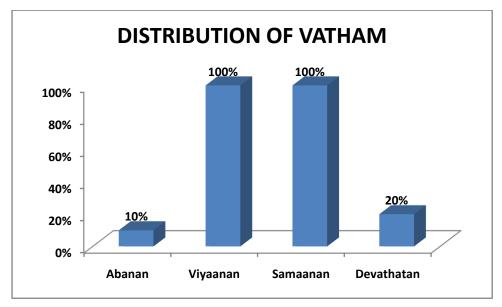
Among the 40 patients, 20 (50%) cases were in normal weight, 12 (30%) cases were in overweight and 8 (20%) cases in obese condition.

13. DISTRIBUTION OF VAATHAM

Table 13

VATHAM	NUMBER OF PATIENTS	PERCENTAGE %
Abanan	4	10%
Viyaanan	40	100%
Samaanan	40	100%
Devathatan	8	20%

Fig no: 13



Observation:

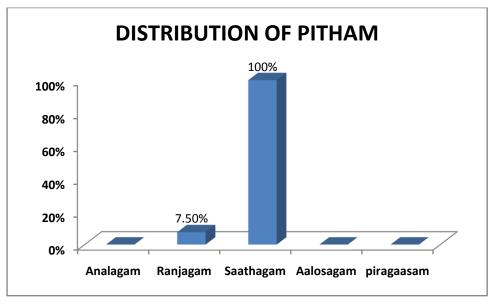
Among the observed 40 cases, Viyaanan and Samanan were affected in almost all the cases (100%) while Abanan was affected in 4 cases (10%) and Devathatan in 8 cases (20%).

14. DISTRIBUTION OF PITHAM

Table 14

PITHAM	NUMBER OF PATIENTS	PERCENTAGE %
Analagam	0	0%
Ranjagam	3	7.5%
Saathagam	40	100%
Aalosagam	0	0%
piragaasam	0	0%





Observation:

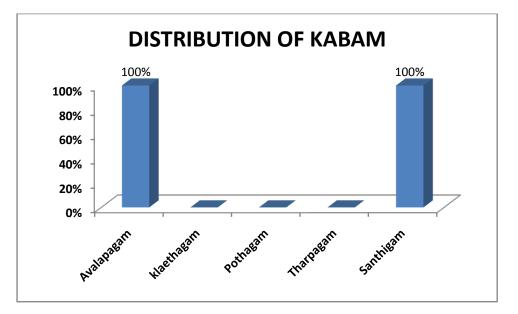
Among the 40 cases, Saathagam was affected in almost all the cases and Ranjagam was affected in 3cases (7.5%).

15. DISTRIBUTION OF KABAM

Table 15:

KABAM	NUMBER OF PATIENTS	PERCENTAGE %
Avalapagam	40	100%
klaethagam	0	0%
Pothagam	0	0%
Tharpagam	0	0%
Santhigam	40	100%





Observation:

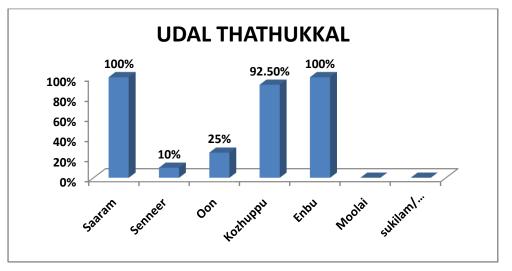
Avalambagam and Santhigam were affected in all the 40 cases.

16. UDAL THAATHUKKAL

Table: 16

UDAL THAATHUKKAL	NUMBER OF PATIENTS	PERCENTAGE %
Saaram	40	100%
Senneer	4	10%
Oon	10	25%
Kozhuppu	37	92.5%
Enbu	40	100%
Moolai	0	0%
sukilam/ suronitham	0	0%





Observation:

Saaram and Enbu were affected in all the 40 cases (100%), Senneer was affected in 4 cases (10%), Oon was affected in cases10 (25%), Kozhuppu was affected in 37 cases (92.5%), moolai and sukilam/suronitham was not affected in all the cases.

17. ENVAGAI THERVUGAL (EIGHT DIAGNOSTIC METHODS)

Table 17

ENVAGAI THERVUGAL	NUMBER OF	PERCENTAGE
	CASES	
Naadi: Vathapitha naadi	22	55%
Pithavatham naadi	8	20%
Pithakabam naadi	2	5%
Kabapitham	8	20%
Naa	0	0%
Niram	0	0%
Mozhi	0	0%
Vizhi	0	0%
Sparisam	0	0%
Malam	4	10%

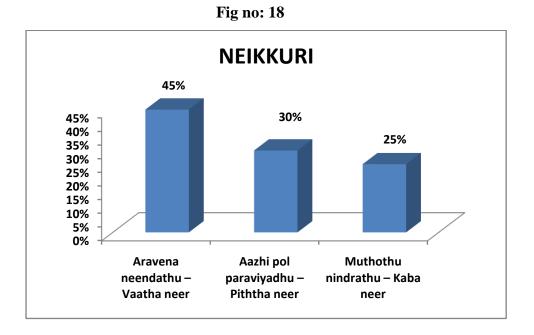
Observation:

Among the 40 patients recruited, Vaathapitha naadi was found in 22 cases (55%), Pithavaatha naadi was found in 8 cases (20%), Pithakaba naadi was found in 2 cases (5%), Kabapitha naadi was found in 8 cases (20%). Malam was affected in 4(10%) of the cases due to constipation.

18. NEIKKURI

Table 18

SPREADING PATTERN	NUMBER OF PATIENTS	PERCENTAGE %		
Aravena neendathu – Vaatha neer	18	45%		
Aazhi pol paraviyadhu – Piththa neer	12	30%		
Muthothu nindrathu – Kaba neer	10	25%		
Total	40	100%		



Observation:

Among 40 cases, Vaatha neer was found in 18 cases (45%), Pitha neer was found in 10 cases (25%) and Kaba neer was found in 12cases (30%).

19.00	I COME BA	SED ON UNIVERS	SAL PA	IN AS	9699	WENT SCALE
S.NO	OP/IP NO	NAME	AGE/	BT	AT	RESULT
			SEX			

19. OUTCOME BASED ON UNIVERSAL PAIN ASSESSMENT SCALE

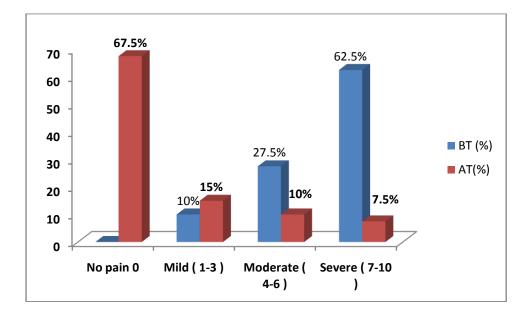
			SEX			
1	H88414	Mrs.Chitra	43/F	7	0	GOOD
2	G60332	Mr. Prakash	41/M	7	0	GOOD
3	I3240	Mrs.Selvi	42/F	5	0	GOOD
4	H96706	Mrs.Madhavi	50/F	10	8	NO IMPROVEMENT
5	I6186	Mrs.Kumari	56/F	10	4	MILD
6	I7514	Mr.Srinivasan	53/M	8	1	GOOD
7	I8998	Mrs.Shyamala gowri	38/F	10	3	MODERATE
8	I9177	Mrs.Amsavalli	38/F	8	1	GOOD
9	H43605	Mrs.Rajeshwari	34/F	6	0	GOOD
10	I16170	Mrs.Kavitha	41/F	8	1	GOOD
11	I14042	Mrs.Amutha	40/F	8	3	MODERATE
12	I22127	Mr.Devaraj	30/M	7	0	GOOD
13	H88529	Mrs.S.Sudha	30/F	9	3	MODERATE
14	I7243	Mrs.Geetha	33/F	8	3	MODERATE
15	I25806	Mr.Lindo	23/F	6	0	GOOD
16	I27407	Mrs.Nazeera	40/F	9	5	MILD
17	I33890	Mrs.Mahalakshmi	36/F	7	1	GOOD
18	I13101	Mrs.Kasthuri	27/F	8	0	GOOD
19	H91313	Mr.Elumalai	46/M	6	0	GOOD
20	I37733	Mr.Velmurugan	54/M	7	1	GOOD

S.NO	OP/IP NO	NAME	AGE/ SEX	BT	AT	RESULT
21	IP8546	Mrs.Shanthi	43/F	7	3	MODERATE
22	I38893	Mrs.Salmabeevi	57/F	4	0	GOOD
23	I20360	Mrs.Malarvizhi	50/F	5	0	GOOD
24	H69278	Mrs.Vijaya	44/F	7	0	GOOD
25	IP8576	Mrs.Chandra	54/F	8	2	MODERATE
26	I53175	Mrs.Padma	36/F	5	0	GOOD
27	I48839	Mrs.Bharathi	54/F	5	0	GOOD
28	I45309	Mrs.S.Sudha	45/F	8	1	GOOD
29	I20358	Mrs.Srividhya	45/F	7	0	GOOD
30	I41992	Mrs.Yasodha	37/F	7	0	GOOD
31	I48370	Mrs.B.Shanthi	54/F	9	9	NO IMPROVEMENT
32	I59044	Mrs.Kalaivani	45/F	7	1	GOOD
33	158557	Mrs.Parameshwar i	36/F	7	4	MILD
34	158557	Mrs.Manjula	43/F	9	6	MILD
35	I59041	Mrs.Poonguzhali	34/F	6	1	GOOD
36	I52794	Mrs.Sundari	40/F	7	0	GOOD
37	I60014	Mrs.Srimathi	48/F	7	1	GOOD
38	G85168	Mrs.Gajalakshmi	30/F	7	1	GOOD
39	I65089	Mrs.Narmadha	53/F	10	9	NO IMPROVEMENT
40	I49734	Mrs.Sasikala	43/F	6	0	GOOD

OUTCOME BASED ON UNIVERSAL PAIN ASSESSMENT SCALE

19. A. UNIVERSAL PAI	N ASSESSMENT SCALE SCORE
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	BEFORE TRI	EATMENT	AFTER TREATMENT			
Pain assesment	Number of patients	Percentage %	Number of patients	Percentage %		
No pain 0	0	0%	27	67.5%		
Mild (1-3)	-3) 4 10%		6	15%		
Moderate (4-6)	11	27.5%	4	10%		
Severe (7-10)	25	62.5%	3	7.5%		
Total	40	100%	40	100%		



Observation:

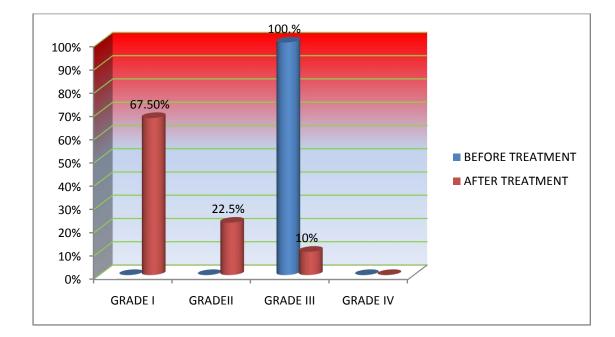
Among the 40 cases, after the treatment the pain was reduced in 27cases (67.5%), mild pain was present in 6 cases (15%), moderate pain was present in 4 cases (10%) and severe pain was present in 3 cases (7.5%).

19. B. RESTRICTED MOVEMENT ASSESSMENT – GRADATION OF MOVEMENTS

S.NO	OP/IP NO	NAME	AGE/SEX	BEFORE TREATMENT	AFTER TREATMENT
1	H88414	Mrs.Chitra	43/F	G3	G1
2	G60332	Mr. Prakash	41/M	G3	G1
3	I3240	Mrs.Selvi	42/F	G3	G1
4	H96706	Mrs.Madhavi	50/F	G3	G3
5	I6186	Mrs.Kumari	56/F	G3	G2
6	I7514	Mr.Srinivasan	53/M	G3	G1
7	I8998	Mrs.Shyamala gowri	38/F	G3	G2
8	I9177	Mrs.Amsavalli	38/F	G3	G1
9	H43605	Mrs.Rajeshwari	34/F	G3	G1
10	I16170	Mrs.Kavitha	41/F	G3	G1
11	I14042	Mrs.Amutha	40/F	G3	G2
12	I22127	Mr.Devaraj	30/M	G3	G1
13	H88529	Mrs.S.Sudha	30/F	G3	G2
14	I7243	Mrs.Geetha	33/F	G3	G2
15	I25806	Mr.Lindo	23/F	G3	G1
16	I27407	Mrs.Nazeera	40/F	G3	G2
17	I33890	Mrs.Mahalakshmi	36/F	G3	G1
18	I13101	Mrs.Kasthuri	27/F	G3	G1
19	H91313	Mr.Elumalai	46/M	G3	G1
20	I37733	Mr.Velmurugan	54/M	G3	G1
21	IP8546	Mrs.Shanthi	43/F	G3	G2
22	I38893	Mrs.Salmabeevi	57/F	G3	G1
23	I20360	Mrs.Malarvizhi	50/F	G3	G1
24	H69278	Mrs.Vijaya	44/F	G3	G1
25	IP8576	Mrs.Chandra	54/F	G3	G2
26	I53175	Mrs.Padma	36/F	G3	G1
27	I48839	Mrs.Bharathi	54/F	G3	G1
28	I45309	Mrs.S.Sudha	45/F	G3	G1
29	I20358	Mrs.Srividhya	45/F	G3	G1
30	I41992	Mrs.Yasodha	37/F	G3	G1
31	I48370	Mrs.B.Shanthi	54/F	G3	G3
32	I59044	Mrs.Kalaivani	45/F	G3	G1
33	158557	Mrs.Parameshwari	36/F	G3	G2
34	158557	Mrs.Manjula	43/F	G3	G3
35	I59041	Mrs.Poonguzhali	34/F	G3	G1
36	I52794	Mrs.Sundari	40/F	G3	G1
37	I60014	Mrs.Srimathi	48/F	G3	G1
38	G85168	Mrs.Gajalakshmi	30/F	G3	G1
39	I65089	Mrs.Narmadha	53/F	G3	G3
40	I49734	Mrs.Sasikala	43/F	G3	G1

19. B. RESTRICTED MOVEMENT ASSESSMENT GRADE

	BEFORE T	REATMENT	AFTER TREATMENT				
GRADING	Number of Percentage		Number of	Percentage			
	patients	%	patients	%			
GRADE I	0	0%	27	67.5%			
GRADE II	0	0%	9	22.5%			
GRADE III	40	100%	4	10%			
GRADE IV	0	0%	0	0%			
TOTAL	40	100%	40	100%			



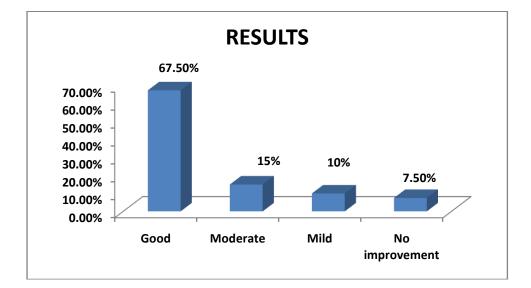
Observation:

Among 40 patients, 27 (67.5%) patients were reported good relief in restriction of movements, 9 (22.5%) patients were reported moderate relief and restriction of movements continued in remaining 4 (10%) of cases.

20. RESULTS

The trial drug *Akkini Chooarnam* (internal) and *Veera mezhugu* (external) were given to 40 patients for 48 days.

RESULTS	NO OF CASES	PERCENTAGE
Good improvement	27	67.5%
Moderate improvement	6	15%
Mild improvement	4	10%
No improvement	3	7.5%



Observation:

The trial drug *Akkini chooranam* (internal) and *Veera mezhugu* (external) were given to 40 patients 48 days. Good improvement were observed in 67.50% of cases, Moderate improvement in 15% of cases, Mild improvement were observed in 10% of cases and no improvement were observed in 7.50% of cases.

LABORATORY INVESTIGATION

				Hb(gm/dl)		TOTAL RBC COUNT (million/c u.mm)		ESR (mm/hour)		TOTAL WBC COUNT	
S.N O	IP/OP NO	NAME	AGE/ SEX	BT	AT	BT	AT	BT	AT	BT	AT
1	H88414	Mrs.Chitra	43/F	12.5	13	3.8	3.8	10	8	6100	6000
2	G60332	Mr. Prakash	41/M	14.2	14.0	5.1	5.1	14	22	6800	6600
3	I3240	Mrs.Selvi	42/F	13.5	138	4.6	4.6	4	8	5100	4500
4	H96706	Mrs.Madhavi	50/F	15.1	15.5	4.5	4.5	4	6	5500	6700
5	I6186	Mrs.Kumari	56/F	13.5	13.8	4.5	4.5	12	8	6500	7000
6	I7514	Mr.Srinivasan	53/M	13.9	14.2	5.0	5.0	10	22	6500	6500
7	I8998	Mrs.Shyamala gowri	38/F	11.3	12.0	4.4	4.4	66	30	10000	8500
8	I9177	Mrs.Amsavalli	38/F	12.5	12.2	4.6	4.2	62	30	7500	7000
9	H43605	Mrs.Rajeshwari	34/F	10	10.2	4.2	4.0	4	8	10200	8500
10	I16170	Mrs.Kavitha	41/F	13.0	13.5	4.0	4.1	10	12	6300	6300
11	I14042	Mrs.Amutha	40/F	12.2	12.4	4.3	4.4	34	40	6100	6300
12	I22127	Mr.Devaraj	30/M	15.9	16.7	6.4	6.4	6	8	5600	5000
13	H88529	Mrs.S.Sudha	30/F	13.7	13.7	4.5	4.5	10	12	6300	6900
14	I7243	Mrs.Geetha	33/F	13.5	13.0	4.5	4.5	12	14	4500	5000
15	I25806	Mr.Lindo	23/F	14.2	15.3	5.0	5.4	16	6	4000	4000
16	I27407	Mrs.Nazeera	40/F	11.9	12.8	5.1	5.3	40	30	6600	6000
17	133890	Mrs.Mahalakshmi	36/F	12.5	12.8	4.5	4.6	6	4	6000	6500
18	I13101	Mrs.Kasthuri	27/F	12.6	12.6	5.2	5.2	34	12	7900	7800
19	H91313	Mr.Elumalai	46/M	15.9	16.2	4.4	4.6	4	12	4400	4200
20	I37733	Mr.Velmurugan	54/M	15.6	15.3	5.1	4.9	6	8	8200	7800

	IKEAIMENI			Hb(gm/dl)		TOTAL RBC COUNT (million/c u.mm)		ESR (mm/hour)		TOTAL WBC COUNT	
S.N O	IP/OP NO	NAME	AGE/ SEX	BT	AT	BT	AT	BT	AT	BT	AT
21	IP8546	Mrs.Shanthi	43/F	10.5	11.5	3.9	3.9	40	38	8000	7600
22	I38893	Mrs.Salmabeevi	57/F	12.8	12.8	4.5	4.5	42	22	8900	7800
23	I20360	Mrs.Malarvizhi	50/F	12.1	12.3	4.6	4.6	16	40	4600	5300
24	H69278	Mrs.Vijaya	44/F	10.2	10.5	4.7	4.5	62	32	7800	7500
25	IP8576	Mrs.Chandra	54/F	11.4	11.6	3.9	3.9	82	80	7400	8600
26	I53175	Mrs.Padma	36/F	12.9	13.0	4.4	4.4	20	22	7300	7400
27	I48839	Mrs.Bharathi	54/F	12.3	12.5	4.0	4.1	24	60	5300	5900
28	I45309	Mrs.S.Sudha	45/F	12.9	12.0	4.5	4.2	24	26	5200	5200
29	I20358	Mrs.Srividhya	45/F	12.5	12.8	4.5	4.5	6	8	5500	6000
30	I41992	Mrs.Yasodha	37/F	12.2	12.2	4.8	4.8	6	6	6600	6300
31	I48370	Mrs.B.Shanthi	54/F	13.5	13.5	4.5	4.5	20	30	4600	4600
32	I59044	Mrs.Kalaivani	45/F	13.3	13.6	4.8	4.8	6	8	8700	6700
33	158557	Mrs.Parameshwari	36/F	12.9	12.9	4.6	4.6	8	4	7700	6500
34	158557	Mrs.Manjula	43/F	12.9	12.9	4.4	4.4	24	20	8000	8000
35	I59041	Mrs.Poonguzhali	34/F	12.9	12.8	4.6	4.6	24	12	9700	7400
36	152794	Mrs.Sundari	40/F	11.5	12.0	4.5	4.5	6	8	4500	6000
37	I60014	Mrs.Srimathi	48/F	13.8	12.8	4.7	4.4	12	60	6500	6300
38	G85168	Mrs.Gajalakshmi	30/F	11.9	12.0	4.7	4.7	20	12	9100	6700
39	I65089	Mrs.Narmadha	53/F	12.5	12.0	4.9	4.9	46	34	10000	1060 0
40	I49734	Mrs.Sasikala	43/F	11.9	11.9	4.3	4.2	32	70	6500	6200

	S ID/OD NAME			BLOOD GLUCOS E(F)		BLOOD GLUCOS E(PP)		UREA		CREATIN INE		TOTAL CHOLES TROL	
S. N O	IP/OP NO	NAME	AGE/ SEX	BT	AT	BT	AT	BT	AT	BT	AT	BT	AT
1	H88414	Mrs.Chitra	43/F	78	78	17	110	15	15	1.1	0.9	197	180
2	G60332	Mr. Prakash	41/M	108	75	115	101	18	17	1.2	1.1	169	158
3	I3240	Mrs.Selvi	42/F	85	75	102	82	16	12	1.0	0.8	138	151
4	H96706	Mrs.Madhavi	50/F	95	90	110	110	16	15	0.9	0.8	165	168
5	I6186	Mrs.Kumari	56/F	90	88	110	99	16	15	0.8	0.8	165	163
6	I7514	Mr.Srinivasan	53/M	107	84	136	98	24	17	1.0	0.9	152	121
7	I8998	Mrs.Shyamala gowri	38/F	91	85	110	100	22	18	1.0	0.8	163	160
8	I9177	Mrs.Amsavalli	38/F	110	81	108	91	22	17	1.0	0.7	194	172
9	H43605	Mrs.Rajeshwari	34/F	90	74	123	109	13	15	0.9	0.9	164	166
10	I16170	Mrs.Kavitha	41/F	92	92	138	119	09	15	1.0	0.9	195	167
11	I14042	Mrs.Amutha	40/F	90	4	86	88	21	18	0.8	0.7	191	164
12	I22127	Mr.Devaraj	30/M	100	88	126	107	17	20	0.8	0.9	162	111
13	H88529	Mrs.S.Sudha	30/F	111	70	140	100	29	21	1.1	0.9	176	157
14	I7243	Mrs.Geetha	33/F	85	90	100	110	16	16	0.8	0.8	155	160
15	I25806	Mr.Lindo	23/F	105	103	114	110	12	15	1.1	0.9	164	145
16	I27407	Mrs.Nazeera	40/F	103	106	100	116	14	13	0.9	0.8	162	154
17	I33890	Mrs.Mahalaksh mi	36/F	80	85	100	125	16	13	0.8	0.7	165	155
18	I13101	Mrs.Kasthuri	27/F	79	105	77	89	13	15	0.7	0.7	147	143
19	H91313	Mr.Elumalai	46/M	88	105	75	110	20	17	0.8	0.8	196	182
20	I37733	Mr.Velmurugan	54/M	75	93	101	100	31	23	1.0	1.0	201	193

	S IP/OP NAME			BLOOD GLUCOS E(F)		BLOOD GLUCOS E(PP)		UREA		CREATIN INE		TOTAL CHOLES TROL	
S. N O	IP/OP NO	NAME	AGE/ SEX	BT	AT	BT	AT	BT	AT	BT	AT	BT	AT
21	IP8546	Mrs.Shanthi	43/F	110	101	120	105	18	15	0.9	0.8	190	189
22	138893	Mrs.Salmabeevi	57/F	71	98	88	105	19	19	0.8	0.8	221	213
23	I20360	Mrs.Malarvizhi	50/F	68	95	77	132	17	17	0.9	0.9	175	147
24	H69278	Mrs.Vijaya	44/F	75	94	87	120	18	15	0.8	0.8	165	170
25	IP8576	Mrs.Chandra	54/F	68	104	135	140	15	14	0.9	0.8	137	170
26	I53175	Mrs.Padma	36/F	77	96	85	140	15	21	0.9	0.9	156	132
27	I48839	Mrs.Bharathi	54/F	84	110	84	113	13	14	0.9	0.8	237	236
28	I45309	Mrs.S.Sudha	45/F	67	94	83	110	19	15	0.8	0.8	160	138
29	120358	Mrs.Srividhya	45/F	80	75	110	100	15	13	0.9	0.8	163	155
30	I41992	Mrs.Yasodha	37/F	87	92	95	115	20	21	0.9	0.9	184	153
31	I48370	Mrs.B.Shanthi	54/F	90	85	110	115	16	15	0.9	0.8	150	150
32	159044	Mrs.Kalaivani	45/F	92	90	108	108	17	20	0.9	0.9	148	171
33	158557	Mrs.Parameshw ari	36/F	92	90	100	100	19	17	0.8	0.7	157	160
34	158557	Mrs.Manjula	43/F	100	90	100	92	12	13	0.7	0.8	185	157
35	I59041	Mrs.Poonguzhal i	34/F	96	98	100	103	11	16	0.8	0.9	149	161
36	152794	Mrs.Sundari	40/F	85	90	100	110	16	16	0.8	0.8	158	150
37	I60014	Mrs.Srimathi	48/F	107	96	110	98	15	17	1.0	1.0	181	197
38	G85168	Mrs.Gajalakshm i	30/F	108	100	114	120	17	17	0.8	0.7	180	178
39	I65089	Mrs.Narmadha	53/F	95	95	112	120	26	24	0.8	0.9	208	200
40	I49734	Mrs.Sasikala	43/F	104	96	134	101	20	20	0.8	0.9	192	192

	<u>EATMEN</u>			TOTA BILIF	AL RUBIN	CAL M	CIU	PHO RUS	SPHO	URIC A	4CID
S.N O	IP/OP NO	NAME	AGE/ SEX	BT	AT	BT	AT	BT	AT	BT	AT
1	H88414	Mrs.Chitra	43/F	0.6	0.5	9.1	9.1	2.8	2.8	5.0	3.5
2	G60332	Mr. Prakash	41/M	0.4	0.4	8.3	8.4	3.7	4.4	9.4	8.2
3	I3240	Mrs.Selvi	42/F	1.4	0.8	9.4	8.2	3.1	3.6	4.5	3.6
4	H96706	Mrs.Madhavi	50/F	0.5	0.6	9.9	9.9	3.5	3.5	5.5	3.9
5	I6186	Mrs.Kumari	56/F	0.4	0.4	8.9	9.2	2.5	3.1	4.5	4.0
6	I7514	Mr.Srinivasan	53/M	0.6	0.5	9.7	9.3	2.9	3.4	6.3	5.2
7	18998	Mrs.Shyamala gowri	38/F	0.6	0.6	8.9	8.5	2.7	2.5	5.8	4.5
8	I9177	Mrs.Amsavalli	38/F	1.2	1.0	9.4	8.6	2.1	4.0	3.3	2.4
9	H43605	Mrs.Rajeshwari	34/F	0.3	0.3	8.4	8.5	3.1	2.9	5.9	6.2
10	I16170	Mrs.Kavitha	41/F	0.4	0.5	8.7	8.7	2.3	3.2	4.1	4.5
11	I14042	Mrs.Amutha	40/F	0.4	0.4	9.0	9.3	2.9	3.6	4.8	3.9
12	I22127	Mr.Devaraj	30/M	1.0	0.8	8.0	8.0	1.8	2.6	6.5	4.6
13	H88529	Mrs.S.Sudha	30/F	0.7	0.9	9.5	9.4	2.3	2.9	3.8	3.1
14	I7243	Mrs.Geetha	33/F	0.4	0.5	9.5	9.2	2.9	2.9	3.5	3.3
15	I25806	Mr.Lindo	23/F	0.6	0.5	8.7	9.2	3.4	3.7	7.9	6.0
16	I27407	Mrs.Nazeera	40/F	0.5	0.6	7.9	8.4	3.7	3.1	5.3	3.6
17	133890	Mrs.Mahalakshmi	36/F	0.3	0.3	9.5	9.3	2.5	2.5	4.5	3.3
18	I13101	Mrs.Kasthuri	27/F	0.9	0.3	8.0	8.1	3.2	2.9	2.4	2.3
19	H91313	Mr.Elumalai	46/M	0.4	0.4	8.8	8.2	4.0	4.0	3.1	3.0
20	I37733	Mr.Velmurugan	54/M	0.4	0.5	8.7	8.1	2.7	2.6	7.6	5.8

	<u>EATMEN</u>			TOTA BILIF	AL RUBIN	CAL	CALCIUM		PHOSPHO RUS		ACID
S.N O	IP/OP NO	NAME	AGE/ SEX	BT	AT	BT	AT	BT	AT	BT	AT
21	IP8546	Mrs.Shanthi	43/F	1.2	1.2	7.9	8.9	3.6	3.8	4.5	3.4
22	I38893	Mrs.Salmabeevi	57/F	0.5	0.5	9.3	9.0	3.7	3.8	4.4	4.1
23	I20360	Mrs.Malarvizhi	50/F	0.3	0.3	8.5	8.7	3.8	2.9	5.7	5.5
24	H69278	Mrs.Vijaya	44/F	0.3	0.4	8.8	8.7	3.1	3.4	4.5	6.8
25	IP8576	Mrs.Chandra	54/F	0.3	0.4	8.2	8.9	3.3	3.7	3.0	3.4
26	I53175	Mrs.Padma	36/F	0.3	0.3	7.8	7.6	3.5	3.2	3.9	4.4
27	I48839	Mrs.Bharathi	54/F	0.7	0.7	8.6	8.5	4.0	3.4	3.0	3.2
28	I45309	Mrs.S.Sudha	45/F	1.0	0.4	8.2	7.6	3.0	2.9	2.9	2.6
29	I20358	Mrs.Srividhya	45/F	0.5	0.4	8.5	8.5	3.4	3.4	4.4	3.4
30	I41992	Mrs.Yasodha	37/F	0.4	0.3	8.7	8.2	3.0	2.7	3.9	3.3
31	I48370	Mrs.B.Shanthi	54/F	0.5	0.6	9.5	9.5	3.8	3.8	4.2	3.8
32	I59044	Mrs.Kalaivani	45/F	1.2	1.3	75	8.8	2.5	3.0	4.0	4.8
33	I58557	Mrs.Parameshwari	36/F	0.9	0.5	8.1	8.2	4.6	4.6	2.3	2.3
34	I58557	Mrs.Manjula	43/F	0.4	0.3	7.5	9.5	2.8	3.3	3.6	3.0
35	I59041	Mrs.Poonguzhali	34/F	0.9	0.7	8.0	10.2	2.4	3.2	4.3	4.3
36	I52794	Mrs.Sundari	40/F	0.2	0.2	9.5	9.8	2.9	3.1	3.8	3.6
37	I60014	Mrs.Srimathi	48/F	0.4	0.4	9.3	8.9	3.0	3.6	3.5	3.9
38	G85168	Mrs.Gajalakshmi	30/F	0.9	0.6	8.4	9.0	3.3	3.5	5.0	4.5
39	I65089	Mrs.Narmadha	53/F	0.5	0.5	8.7	8.8	2.9	3.0	3.9	4.5
40	I49734	Mrs.Sasikala	43/F	0.4	0.4	7.9	8.6	3.7	3.7	5.7	5.5

		-		SGO	Γ	SGP	T		ALINE SPHAT
S.N O	IP/OP NO	NAME	AGE/ SEX	BT	AT	BT	AT	BT	AT
1	H88414	Mrs.Chitra	43/F	17	17	20	20	76	76
2	G60332	Mr. Prakash	41/M	20	43	34	27	73	52
3	I3240	Mrs.Selvi	42/F	17	11	18	08	44	39
4	H96706	Mrs.Madhavi	50/F	18	15	15	15	75	75
5	I6186	Mrs.Kumari	56/F	17	15	18	17	65	70
6	I7514	Mr.Srinivasan	53/M	19	21	23	25	81	64
7	18998	Mrs.Shyamala gowri	38/F	11	15	19	20	96	98
8	I9177	Mrs.Amsavalli	38/F	40	18	32	14	100	62
9	H43605	Mrs.Rajeshwari	34/F	11	14	14	15	69	61
10	I16170	Mrs.Kavitha	41/F	19	22	18	15	72	61
11	I14042	Mrs.Amutha	40/F	18	14	11	09	82	81
12	I22127	Mr.Devaraj	30/M	17	27	21	29	74	73
13	H88529	Mrs.S.Sudha	30/F	17	15	19	20	75	73
14	I7243	Mrs.Geetha	33/F	18	18	20	22	85	89
15	I25806	Mr.Lindo	23/F	23	17	25	17	95	92
16	I27407	Mrs.Nazeera	40/F	19	14	16	14	71	71
17	I33890	Mrs.Mahalakshmi	36/F	17	17	18	18	83	87
18	I13101	Mrs.Kasthuri	27/F	15	13	06	09	62	74
19	H91313	Mr.Elumalai	46/M	18	18	18	18	80	82
20	I37733	Mr.Velmurugan	54/M	19	19	27	26	79	80

		<u>.</u>		SGO	Γ	SGP			ALINE SPHAT
S.N O	IP/OP NO	NAME	AGE/ SEX	BT	AT	BT	AT	BT	AT
21	IP8546	Mrs.Shanthi	43/F	15	15	14	13	58	57
22	I38893	Mrs.Salmabeevi	57/F	14	15	13	15	67	74
23	I20360	Mrs.Malarvizhi	50/F	20	16	13	15	52	52
24	H69278	Mrs.Vijaya	44/F	34	31	15	16	80	70
25	IP8576	Mrs.Chandra	54/F	12	10	10	17	50	55
26	I53175	Mrs.Padma	36/F	10	10	11	12	42	44
27	I48839	Mrs.Bharathi	54/F	14	15	21	16	61	61
28	I45309	Mrs.S.Sudha	45/F	21	15	24	14	138	118
29	I20358	Mrs.Srividhya	45/F	15	19	18	20	85	90
30	I41992	Mrs.Yasodha	37/F	19	15	09	12	56	65
31	I48370	Mrs.B.Shanthi	54/F	15	15	20	18	80	85
32	159044	Mrs.Kalaivani	45/F	09	12	15	14	52	54
33	158557	Mrs.Parameswari	36/F	15	16	17	17	75	80
34	158557	Mrs.Manjula	43/F	16	15	27	18	88	92
35	I59041	Mrs.Poonguzhali	34/F	26	26	30	30	80	80
36	152794	Mrs.Sundari	40/F	17	15	16	18	150	158
37	I60014	Mrs.Srimathi	48/F	18	2	15	22	75	75
38	G85168	Mrs.Gajalakshmi	30/F	17	17	21	21	80	80
39	I65089	Mrs.Narmadha	53/F	13	15	17	16	107	118
40	I49734	Mrs.Sasikala	43/F	14	14	14	14	93	103

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S. N O	IP/OP NO	NAME	AGE/ SEX	BT	AT	BT	AT	BT	AT	BT	AT	BT	AT		
1	H88414	Mrs.Chitra	43/F	NIL	NIL	NIL	NIL	NIL	NIL	1-3	1-3	1-2	1-2		
2	G60332	Mr. Prakash	41/M	NIL	NIL	NIL	NIL	NIL	NIL	1-3	1-3	1-3	1-3		
3	I3240	Mrs.Selvi	42/F	NIL	NIL	NIL	NIL	NIL	NIL	1-3	1-3	1-2	1-2		
4	H96706	Mrs.Madhavi	50/F	NIL	NIL	NIL	NIL	NIL	NIL	2-3	1-3	1-2	1-2		
5	I6186	Mrs.Kumari	56/F	NIL	NIL	NIL	NIL	NIL	NIL	1-3	1-3	1-3	1-3		
6	I7514	Mr.Srinivasan	53/M	NIL	NIL	NIL	NIL	NIL	NIL	2-4	2-4	1-3	1-2		
7	18998	Mrs.Shyamala gowri	38/F	NIL	NIL	NIL	NIL	NIL	NIL	1-3	1-4	1-2	1-3		
8	I9177	Mrs.Amsavalli	38/F	NIL	NIL	NIL	NIL	NIL	NIL	1-3	1-3	1-2	1-2		
9	H43605	Mrs.Rajeshwari	34/F	NIL	NIL	NIL	NIL	NIL	NIL	1-3	1-3	2-3	2-3		
10	I16170	Mrs.Kavitha	41/F	NIL	NIL	NIL	NIL	NIL	NIL	2-4	2-4	1-3	1-3		
11	I14042	Mrs.Amutha	40/F	NIL	NIL	NIL	NIL	NIL	NIL	2-4	2-4	1-3	1-2		
12	I22127	Mr.Devaraj	30/M	NIL	NIL	NIL	NIL	NIL	NIL	2-3	1-2	2-3	1-2		
13	H88529	Mrs.S.Sudha	30/F	NIL	NIL	NIL	NIL	NIL	NIL	4-6	4-6	2-3	2-3		
14	I7243	Mrs.Geetha	33/F	NIL	NIL	NIL	NIL	NIL	NIL	1-3	1-3	1-2	1-2		
15	125806	Mr.Lindo	23/F	NIL	NIL	NIL	NIL	NIL	NIL	1-3	1-3	2-3	2-3		
16	I27407	Mrs.Nazeera	40/F	NIL	NIL	NIL	NIL	NIL	NIL	3-5	1-2	1-3	1-3		
17	I33890	Mrs.Mahalaksh mi	36/F	NIL	NIL	NIL	NIL	NIL	NIL	1-3	1-4	2-3	2-3		
18	I13101	Mrs.Kasthuri	27/F	NIL	NIL	NIL	NIL	NIL	NIL	2-3	2-3	1-2	1-2		
19	H91313	Mr.Elumalai	46/M	NIL	NIL	NIL	NIL	NIL	NIL	1-2	1-2	1-2	1-2		
20	I37733	Mr.Velmurugan	54/M	NIL	NIL	NIL	NIL	NIL	NIL	1-2	1-2	1-3	1-3		

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S. N O	IP/OP NO	NAME	AGE/ SEX	BT	AT	BT	AT	BT	AT	BT	AT	BT	AT
21	IP8546	Mrs.Shanthi	43/F	NIL	NIL	NIL	NIL	NIL	NIL	1-3	1-5	1-2	1-3
22	I38893	Mrs.Salmabeevi	57/F	NIL	NIL	NIL	NIL	NIL	NIL	1-2	1-2	1-3	1-3
23	I20360	Mrs.Malarvizhi	50/F	NIL	NIL	NIL	NIL	NIL	NIL	1-2	1-3	1-2	1-2
24	H69278	Mrs.Vijaya	44/F	NIL	NIL	NIL	NIL	NIL	NIL	2-4	4-5	3-5	1-3
25	IP8576	Mrs.Chandra	54/F	NIL	NIL	NIL	NIL	NIL	NIL	1-3	1-3	1-2	1-2
26	I53175	Mrs.Padma	36/F	NIL	NIL	NIL	NIL	NIL	NIL	1-2	1-2	2-3	2-3
27	I48839	Mrs.Bharathi	54/F	NIL	NIL	NIL	NIL	NIL	NIL	1-3	1-3	1-2	1-2
28	I45309	Mrs.S.Sudha	45/F	NIL	NIL	NIL	NIL	NIL	NIL	1-2	1-2	1-3	2-5
29	I20358	Mrs.Srividhya	45/F	NIL	NIL	NIL	NIL	NIL	NIL	1-3	1-3	2-3	2-3
30	I41992	Mrs.Yasodha	37/F	NIL	NIL	NIL	NIL	NIL	NIL	1-2	2-3	2-3	3-4
31	I48370	Mrs.B.Shanthi	54/F	NIL	NIL	NIL	NIL	NIL	NIL	1-3	1-5	1-2	1-2
32	I59044	Mrs.Kalaivani	45/F	NIL	NIL	NIL	NIL	NIL	NIL	2-4	2-4	1-3	1-3
33	158557	Mrs.Parameshw ari	36/F	NIL	NIL	NIL	NIL	NIL	NIL	1-3	1-3	1-2	1-2
34	I58557	Mrs.Manjula	43/F	NIL	NIL	NIL	NIL	NIL	NIL	1-2	4-6	2-3	2-3
35	I59041	Mrs.Poonguzhal i	34/F	NIL	NIL	NIL	NIL	NIL	NIL	1-3	1-3	2-4	2-3
36	I52794	Mrs.Sundari	40/F	NIL	NIL	NIL	NIL	NIL	NIL	1-4	1-5	2-3	1-3
37	I60014	Mrs.Srimathi	48/F	NIL	NIL	NIL	NIL	NIL	NIL	1-3	1-4	2-4	1-2
38	G85168	Mrs.Gajalakshm i	30/F	NIL	NIL	NIL	NIL	NIL	NIL	1-3	1-3	1-2	1-2
39	I65089	Mrs.Narmadha	53/F	NIL	NIL	NIL	NIL	NIL	NIL	1-3	1-3	1-2	1-2
40	I49734	Mrs.Sasikala	43/F	NIL	NIL	NIL	NIL	NIL	NIL	1-3	1-3	1-2	1-2

STATISTICAL ANALYSIS

Statistical Analysis

All collected data were entered into MS Excel software using different columns as variables and rows as patients. SPSS software was used to perform statistical analysis. Basic descriptive statistics include frequency distributions and cross-tabulations were performed. The quantity variables were expressed as Mean \pm Standard Deviation and qualitative data as percentage. A probability value of <0.05 was considered to indicate as statistical significance. Paired't' test was performed for determining the significance between before and after treatment.

PAIN ASSESSMENT SCALE BEFORE AND AFTER TREATMENT

Pain scale	Sample size	Mean±	T Value	P value
		Standard		
		Deviation		
Before	40	7.3±1.48		
treatment			19.8	<0.0001
After	40	1.8±2.52		
treatment				

Table: Statistical Significance Of Treatment On Pain

There was a significant difference between before and after treatment on Pain in pain score i.e., significant reduction - 75% in after treatment.

DISCUSSION

DISCUSSION

The Retrospective review of the disease *Kuthikaal vaatham* mentioned in Siddha literatures begins from the correlation of its signs and symptoms of the disease with Plantar Fasciitis.

The drugs which possess anti-vaatha property as mentioned in Siddha literature were selected and the trial drugs were prepared by the Author in the Gunapadam practical laboratory of National Institute of Siddha, after getting proper authentication of raw drugs from the Medicinal Botany Department under the supervision of the members of the faculties and guided by the Head of the Department of Sirappu Maruthuvam of the National Institute of Siddha, Chennai - 47.

40 patients of both genders were recruited for this study. The treatment was aimed to normalizing the deranged thodams and providing relief from symptoms. Before treatment the patients were advised to take Meganatha Kuligai – 2 pills with hot water in empty stomach at early morning for purgation. The patient was advised to take rest without internal medicine and other activities on that day.

From next day onwards the patients were treated with trial drugs '*Akkini Chooranam*' twice a day with hot water and *Veera Mezhugu* external for 48 days. Patients were instructed to take the Medicines regularly advised to follow pathiyam (avoid tamarind, tubers, etc) and advised to avoid weight bearing, and prolonged standing. Out-Patients were asked to visit the hospital once in 7 days. For Out-Patients the drugs were given for 48 days and the clinical assessment was done under the supervision of the faculty on 1st day, 8th day, 15th day, 22th day , 29th day, 36th day, 43th day and 49th day. For In-Patients the trial drugs were given for 48 days and the clinical assessment was done daily. For In-Patients, who are not in a situation to stay in the hospital for a long time, were advised to attend the Out-Patient Department of Sirappu Maruthuvam for further follow- up.

After the fulfillment of treatment, the patients were advised to visit the Out-Patient Department of Sirappu Maruthuvam for further follow-up.

Among the 40 cases, 6 (15%) cases were males and 34 (85%) cases were females. In this study majority affected sex is female (85%). The one of the common cause for this may be depletion of calcium from their body and increased house hold works. From history taking these were concluded as the reasons for female predominance.

This study shows that the highest age distribution of Kuthikaal Vaatham is between 41-50 years of age.

Most of the patients under this analysis were predominantly of Raso gunam assessed from interrogation and other observations.

Most of the patients 36 (90%) were non vegetarians. Non vegetarian diet may be the cause for deposition of fat in adipose tissue and there by promoting obesity. This alters the weight transferring mechanism in heel, causing this disease.

In **Vaatham** Viyanan and Samanan were affected in all 40 cases. Abanan was affected in 4 cases and Devathathan in 8 cases.

In **Pitham** Saathaga pitham was affected in all the 40 cases. Ranjaga pitham was affected in 3 cases.

In Kabam Avalambagam and Santhigam was affected in all the 40 cases.

All cases were observed and examined by the eight clinical parameters of Siddha system.

Naadi (Pulse reading) was observed in all 40 patients. 22 cases had Vaathapittham, 8 cases had Pithavatham, 2 cases had Pithakabam and 8 cases had Kabapitham naadi.

In Malam 4 cases (10%) had constipation.

The color of the **urine** was Elamanjal niram (Pale yellow coloured urine) and Manjal (dark yellow).

In **Neikkuri (Oil on urine sign)** examination, oil spreads slowly in 18 cases indicates vitiation of vatham in the Kuthikaal vaatham patients, in 12 cases it appeared like ring form and in rest of the 10 cases oil acquired as a pearl shape. This reveals that most of the cases had derangement in vaatham.

In Seven Udal kattugal Enbu and Saaram were affected in all 40 cases (100%), Senneer was affected in 4 cases (10%), Oon was affected in 10 cases (4%) Kozhuppu was affected in 37 cases (92.5%) and Enbu was affected in 40 (100%) cases.

In **clinical features** Heel pain and early morning pain were present in all the 40 cases. 35 cases (87.5%) had tenderness in heel region with limitation of movements. The other important features were stiffness in 12 cases (30%) and Exacerbation of pain on movements in 37 cases (92.5%).

Already it was explained that aging is the most common cause for Kuthikaal vaatham. Apart from that, increased household works, Obesity and menopause are the other precipitating factors. Household work accounts for the highest number 16 (40%) of cases. Laboratory investigation of blood and urine were done for all 40 cases. There were no significant changes in blood and urine parameters before and after treatment. In serum uric acid level is decreased in some of the cases are noted in the trial.

The radiographic study does not show any changes in plantar fasciitis. It helps to detect calcaneal spur and other heel pathologies. The trial drug showed improvement in prognosis of the disease clinically.

On the basis of curative effect of the trial drugs, Good improvement was assessed in 27 Patients (67.5%), Moderate improvement was assessed in 6 patients (15%), Mild improvement in 4 patients (10%) and No improvement was assessed in 3 patients (7.5%).

Based on the Restricted movement assessment scale, among 40 patients, 27 (67.5%) patients were reported good relief in restriction of movements, 9 (22.5%) patients were reported moderate relief and restriction of movements continued in remaining 4 (10%) of cases.

SUMMARY

SUMMARY

The Protocol of this study has been submitted to IEC of NIS on 26-8-2015 and then approval was got from IEC for conducting this clinical study. The IEC NO is NIS/IEC/9/2014-15/13.

This study was registered in Clinical Trial Registry of India and the registration number of the Trial is CTRI/2017/06/008931.

The 40 cases of Kuthikaal Vaatham were Screened and diagnosed clinically and treated in Outpatient and In-patient Department of Sirappu Maruthuvam in Ayothidoss Pandithar Hospital attached to National Institute of Siddha, Tamabaram Sanatorium and Chennai – 47.

The various Siddha methods of examination of the disease were carried out and the data were recorded in the prescribed Proforma for the 40 selected cases.

The day before starting treatment purgation was given with Meganatha Kuligai-2 pills in hot water at early morning.

From the first day onwards Akkini Chooranam 1.5gm (twice a day) along with hotwater was given internally and Veeramezhugu (Q.S) for external use were given to the patients.

During the period of treatment all the patients were put under Pathiyam (specific dietary regimen chat for the disease given to each patient.

Laboratory investigations were done periodically for all the cases before and after treatment and radiological investigations were done for all the cases before treatment.

The observations made during the clinical study showed that internal and external drugs were effective in relieving the pain in Kuthikaal vaatham patients. During the study period, there was no adverse event reported. As per the Siddha Literature and recent research articles, the ingredients of the trial drugs was found to have anti inflammatory, Immunomodulator, Anti- oxidant, Analgesic properties owing to the disease manifestations.

Phytochemical analysis which indicates the presence of tannic acid, calcium, chloride has a role in strengthening the bone matrix.

Based on the statistical significance, it was observed by the pain scale there is a reduction of heel pain reduced from 7.3 ± 1.48 to 1.48 ± 2.52 mean value with significant P value of <0.0001.

Hence the trial medicine may effective for *Kuthikaal Vaatham*. Statistical analysis showed significant reduction in the pain score before and after treatment.

The outcome of the trial medicine assessed by pain scale and the results were as follows:

Good improvement	-	27 patients (67.5%)
Moderate improvement	-	6 patients (15%)
Mild improvement	-	4 patients (10%)
No improvement	-	3 patients (7.5%)

CONCLUSION

Conclusion

The clinical trial proves the efficacy of the trail drugs by reducing the clinical signs and symptoms like heel pain, early morning pain, restricted movements and provides better improvement. The study results show that 3 (7.5%) of them had no improvement, 4 (10%) of them had mild improvement, 6 (15%) of them had moderate improvement and 27 (67.5%) of them had good improvement. Hence these results revealed good relief from the disease after treatment.

The trial Medicines were prepared from easily available ingredients and the palatability of medicine is better and the dosage is also convenient.

In this study, there was no adverse effects were reported in clinical trial. Hence the trial drugs were proven for their safety. The clinical trial conducted in selected patients was satisfactory encouraging. Further studies may be taken up to establish the efficacy of the drugs.

ANNEXURE

CERTIFICATES



NATIONAL INSTITUTE OF SIDDHA राष्ट्रीय सिद्ध संसथान

Department of AYUSH- MINISTRY OF HEALTH & FAMILY WELFARE आयुष विभाग - स्वास्थ एवं परिवार कल्याण गंत्रालय GOVERNMENT OF INDIA-शास्त सरकार

TAMBARAM SANATORIUM, CHENNAI -600 047 -ताम्बरम राजटोरियम चेन्नई -600 047

फ़ोन\Tele : 044-22411611

र्फेक्स\Fax : 22381314 वेब :<u>www.nischennai.org</u>

ईमेल: <u>nischennaisiddha@yahoo.co.in</u>

Dt: 05.10.2015

F.No.NIS/6-20/IEC/15-16

CERTIFICATE

Address of Ethics Committee: National Institute of Siddha, Tambaram Sanatorium, Chennai-600047, Tamil Nadu, India

Principal Investigator: Dr.M.Padmavathi, Department of Sirappu Maruthuvam

Protocol title: "An open clinical trial of Siddha drug Akkini Choornam (Internal medicine) and Veera Mezhugu (External medicine) in the Treatment of Kuthikaal Vaatham (Plantar Fasciitis) "

Documents filed	1) Protocol, 2) Data Collection forms 3) SAE(Pharmacovigilance)
Clinical trial Protocol (others – Specify)	Yes
Informed consent documents	Yes
Any other documents	-
Date of IEC approval & its number	NIS/IEC/9/2014-15/13 - 26.08.2015

We approve the trial to be conducted in its presented form.

The Institutional Ethics Committee expects to be informed about the progress of the study, any SAE occurring in the course of the study.

9 Chairman

Member Secretary

NATIONAL INSTITUTE OF SIDDHA, CHENNAI - 600047

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BOTANICAL CERTIFICATE

Certified that the following plant drugs used in the Siddha formulation "Akkini Choornam" (Internal) and "Veera Mezhugu" (External) for Kuthikaal Vaatham taken up for Post Graduation Dissertation studies by Dr. M.Padmavathi, M.D.(S), II year, Department of Sirappu Maruthuvam, 2016, are identified through Visual inspection, Experience, Education & Training, Organoleptic characters, Morphology, Micromorphology and Taxonomical methods as

Plumbago zeylanica Linn. (Plumbaginaceae), Root Zingiber officinale Rosc. (Zingiberaceae), Dried rhizome Piper nigrum Linn. (Piperaceae), Fruit Piper longum Linn. (Piperaceae). Fruit Carum copticum Benth. & Hook. f. (Apiaceae), Fruit Clerodendrum serratum (Linn.) Moon (Verbenaceae), Root Scindapsus officinalis Schott. (Araceae), Fruits Costus speciosus (Koen.) Sm. (Costaceae), Root Ferula foetida Regel. (Apiaceae), Gum-oleoresin Acorus calamus Linn. (Araceae), Rhizome Brassica juncea (Linn.) Czern. & Coss. (Brassicaceae), Seed



Aificate No: NISMB2512016

Date: 12-9-2016

Authorized Signatory Dr. D. ARAVIND, M.D.(s), M.Sc., Assistant Professor Department of Medicinal Botany National Institute of Siddha Chennai - 600 047, INDIA



சித்த மருத்துவ மைய அராய்ச்சி நிலையம்,

சென்னை – 600 106

सिद्ध केंद्रीय अनुसन्धान संस्थान, अण्णा सरकारी अस्पताल परिसर, अरुम्बाक्कम, चेन्नई - ६००१०६

SIDDHA CENTRAL RESEACH INSTITUTE

(Central Council for Research in Siddha, Ministry of AYUSH, Govt. of India) Anna Govt. Hospital Campus, Arumbakkam, Chennai – 600106 Phone: 044-2621 4925, Fax: 044-2621 4809 www.crisiddha.tn.nic.in, Email: crisiddha@gmail.com

08.7.2010

CERTIFICATE

Certified that the samples submitted for identification by Dr. M. Padmavathi, II year MD Student, Department of Sirappu Maruthuvam, National Institute of Siddha, Chennai-600 047 are identified as Inthuppu – Sodium chloride (Impure), Sottruppu – Sodium chloride and Veerum – Mercuric chloride.

(R. Shakila) Research Officer (Chemistry)

(Dr. P. Sathiyarajeswaran) Assistant Director (Scientist 2) I/c

डॉ. पी. सत्तियराजेस्वरण/Dr. P. Sathiyarajeswaran प्रभारी सहायक निदेशक (एस-II)/Assistant Director (S-II) I/C सिद्ध केंद्रीय अनुसंधान संस्थान, अण्णा सरकारी अस्पताल परिसर, अरुम्बाककम, चेन्नई-600 106 SIDDHA CENTRAL RESEARCH INSTITUTE (Central Council for Research in Suddha, Ministry of AYUSH, Govt. of India) Anna Govt. Hospital Campus, Arumbakkam, Chennai 600106



CASE SHEET PROFORMA

DEPARTMENT OF SIRAPPU MARUTHUVAM

AN OPEN CLINICAL TRIAL OF SIDDHA DRUG "AKKINI CHOORANAM" (INTERNAL) AND "VEERA MEZHUGU" (EXTERNAL) IN THE TREATMENT OF "KUTHIKAAL VAATHAM" (PLANTAR FASCIITIS).

Principal Investigator: Dr.M.Padmavathi.

FORM I - SCREENING & SELECTION PROFORMA

1. SERIAL NO:	2. OP /IP NO:
3. NAME:	4. AGE/GENDER:
5. OCCUPATION:	6. INCOME:

INCLUSION CRITERIA

• Whether age is between 20-60	YES\ NO
• Sex	$\mathbf{M} \setminus \mathbf{F}$
• Pain in Heel region.	YES\ NO
Restricted movements.	YES\ NO
• Willing to attend OPD or admission in IPD for the trial	YES\ NO
Willingness for consent	YES\ NO
• Willing to give specimen of blood for the investigation	YES\ NO
Willing to undergo radiological investigation	YES\ NO

EXCLUSION CRITERIA

Cardiac disease	YES\ NO
Diabetes mellitus	YES\ NO
Rheumatoid arthritis	YES\ NO
• Septic arthritis	YES\ NO
Gonococcal arthritis	YES\ NO
Psoriatic arthritis	YES\ NO
Pregnancy and lactation	YES\ NO
Chronic kidney disease	YES\ NO
• Patient with any other serious systemic illness	YES\ NO

ADMITTED TO TRAIL

NO	YES
IPD	If Yes, OPD
Serial NO:	

Date: Station: Signature of the Investigator: Signature of the Faculty:

Signature of the HOD

DEPARTMENT OF SIRAPPU MARUTHUVAM

AN OPEN CLINICAL TRIAL OF SIDDHA DRUG"AKKINI CHOORANAM" (INTERNAL) AND "VEERA MEZHUGU" (EXTERNAL) IN THE TREATMENT OF "KUTHIKAAL VAATHAM" (PLANTAR FASCIITIS).

Principal Investigator: Dr.M.Padmavathi

STUDY NO: NAME: **ADDRESS:**

OCCUPATION: MARITAL STATUS : 1. Married DATE OF INTIAL ASSESSMENT: **COMPLAINTS & DURATION:**

OP / IP NO: AGE / GENDER: **CONTACT NO : RELIGION:** H/C/M/O. **INCOME:** 2. Unmarried

FORM II-A – HISTORY TAKING PROFORMA

PERSONAL HISTORY:

PERSONAL HABITS	YES	NO	IF YES SPECIFY DURATION	AMOUNT/Qty
Smoking				
Tobacco Chewing				
Alcohol				
Narcotic Drug Addiction				

HISTORY OF PREVIOUS ILLNESS AND TREATMENT TAKEN:

FAMILY HISTORY:

Whether this problem runs in family? 1. Yes If yes, mention the relationship of affected 1._____ person(s) 2._____

DIETARY STYLE:

1. Vegetarian 2. Non-vegetarian

2. No

MENSTURAL AND OBSTETRIC HISTORY:

FORM -- II B

:

:

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•

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:

:

:

:

:

:

GENERAL EXAMINATION:

- 1. Body weight [Kg]
- 2. Height [cms]
- 3. Body Temperature [F]
- 4. Blood Pressure (mm/Hg)
- 5. Pulse Rate /min.
- 6. Heart Rate / min.
- 7. Respiratory Rate /min.
- 8. Pallor
- 9. Jaundice
- 10. Clubbing
- 11. Cyanosis
- 12. Pedal Oedema 13. Lymphadenopathy

14. Jugular venous pulsation

Yes

No

SYSTEMIC EXAMINATION

Cardiovascular system	:
Respiratory system	:
Gastro-intestinal system	:
Central Nervous system	:
Urogenital system	:
Endocrine system	:

SIDDHA SYSTEM OF EXAMINATION

1. THEGI (BODY CONSTITUTION):

- 1. Vatha udal
- 2. Pitha udal
- 3. Kaba udal
- 4. Thontha udal

2. NILAM (LAND WHERE THE PATIENT LIVED MOST):

- 1. Kurinji (Hilly terrain)
- 2. Mullai (Forest range)
- 3. Marutham (Plains)
- 4. Neithal (Coastal belt)
- 5. Paalai (Aridregion)

3. KAALAM:

- 1. Kaar kaalam (Aavani-Purattasi)
- 2. Koothir kaalam (Ippasi-Kaarthigai)
- 3. Munpani kaalam (Maargazhi-Thai)
- 4. Pinpani kaalam (Maasi-Panguni)
- (Chithirai-Vaigasi) 5. Ilavenil kaalam
- 6. Muthuvenil kaalam (Aani-Aadi)

		_	

4. GUNAM:

- 1. Saththuvam
- 2. Rasatham
- 3. Thamasam

5. PORIPULANGAL (SENSORY ORGANS):

	Before treatment	After treatment
Mei (Skin)	Normal / Affected	Normal / Affected
Vai (Tongue)	Normal / Affected	Normal / Affected
Kann (Eye)	Normal / Affected	Normal / Affected
Mooku (Nose)	Normal / Affected	Normal / Affected
Sevi (Ear)	Normal / Affected	Normal / Affected

6.KANMENDRIYAM (MOTOR ORGANS) :

	Before treatment	After treatment
Kai(Upper limb)	Normal /Affected	Normal /Affected
Kaal (Lower limb)	Normal /Affected	Normal /Affected
Vai (Oral cavity)	Normal /Affected	Normal /Affected
Eruvai (Anal reg.)	Normal /Affected	Normal /Affected
Karuvai (Uro-	Normal /Affected	Normal /Affected
genital region)		

7.KOSANGAL (SHEATH):

	Before treatment	After treatment
Annamaya kosam	Normal /Affected	Normal /Affected
Pranamaya kosam	Normal /Affected	Normal /Affected
Manomaya kosam	Normal /Affected	Normal /Affected
Vignanamaya kosam	Normal /Affected	Normal /Affected
Ananthamaya kosam	Normal /Affected	Normal /Affected

8. SEVEN UDAL THAATHUKKAL (SEVEN SOMATIC COMPONENTS)

	Before treatment	After treatment
Saaram	Normal /Affected	Normal /Affected
Senneer	Normal /Affected	Normal /Affected
Oon	Normal /Affected	Normal /Affected
Kozhuppu	Normal /Affected	Normal /Affected
Enbu	Normal /Affected	Normal /Affected
Moolai	Normal /Affected	Normal /Affected
Sukkilam / Suronitham	Normal /Affected	Normal /Affected

9. UYIR THAATHUKKAL: [THREE HUMORS] (VALI/ AZHAL/ IYYAM)

A) VALI

	0 th day	8 th day	15 th day	22 nd day	29 th day	36 th day	43 rd day	49 th day
Praanan	Normal	Normal	Normal	Normal	Normal	Normal	Normal	Normal
1 I aanan	/Affected	/Affected	/Affected	/Affected	/Affected	/Affected	/Affected	/Affected
Abaaran	Normal	Normal	Normal	Normal	Normal	Normal	Normal	Normal
Abaanan	/Affected	/Affected	/Affected	/Affected	/Affected	/Affected	/Affected	/Affected
Samaanan	Normal	Normal	Normal	Normal	Normal	Normal	Normal	Normal
Samaanan	/Affected	/Affected	/Affected	/Affected	/Affected	/Affected	/Affected	/Affected
Udhaanan	Normal	Normal	Normal	Normal	Normal	Normal	Normal	Normal
Uunaanan	/Affected	/Affected	/Affected	/Affected	/Affected	/Affected	/Affected	/Affected
Vivoonon	Normal	Normal	Normal	Normal	Normal	Normal	Normal	Normal
Viyaanan	/Affected	/Affected	/Affected	/Affected	/Affected	/Affected	/Affected	/Affected
Naagan	Normal	Normal	Normal	Normal	Normal	Normal	Normal	Normal
Naagan	/Affected	/Affected	/Affected	/Affected	/Affected	/Affected	/Affected	/Affected
Vaamman	Normal	Normal	Normal	Normal	Normal	Normal	Normal	Normal
Koorman	/Affected	/Affected	/Affected	/Affected	/Affected	/Affected	/Affected	/Affected
Vinulaanan	Normal	Normal	Normal	Normal	Normal	Normal	Normal	Normal
Kirukaran	/Affected	/Affected	/Affected	/Affected	/Affected	/Affected	/Affected	/Affected
Devathathan	Normal	Normal	Normal	Normal	Normal	Normal	Normal	Normal
Devathathan	/Affected	/Affected	/Affected	/Affected	/Affected	/Affected	/Affected	/Affected
Dhaman	Normal	Normal	Normal	Normal	Normal	Normal	Normal	Normal
Dhananjeyan	/Affected	/Affected	/Affected	/Affected	/Affected	/Affected	/Affected	/Affected

B) AZHAL

	0 th day	8 th day	15 th day	22 nd day	29 th day	36 th day	43 rd day	49 th day
Analakam	Normal	Normal	Normal	Normal	Normal	Normal	Normal	Normal
	/Affected	/Affected	/Affected	/Affected	/Affected	/Affected	/Affected	/Affected
Ranjakam	Normal	Normal	Normal	Normal	Normal	Normal	Normal	Normal
	/Affected	/Affected	/Affected	/Affected	/Affected	/Affected	/Affected	/Affected
Saathakam	Normal	Normal	Normal	Normal	Normal	Normal	Normal	Normal
	/Affected	/Affected	/Affected	/Affected	/Affected	/Affected	/Affected	/Affected
Prasakam	Normal	Normal	Normal	Normal	Normal	Normal	Normal	Normal
	/Affected	/Affected	/Affected	/Affected	/Affected	/Affected	/Affected	/Affected
Aalosakam	Normal	Normal	Normal	Normal	Normal	Normal	Normal	Normal
	/Affected	/Affected	/Affected	/Affected	/Affected	/Affected	/Affected	/Affected

C) IYYAM

	0 th day	8 th day	15 th day	22 nd day	29 th day	36 th day	43 rd day	49 th day
Avalambagam	Normal	Normal	Normal	Normal	Normal	Normal	Normal	Normal
	/Affected	/Affected	/Affected	/Affected	/Affected	/Affected	/Affected	/Affected
Kilethagam	Normal	Normal	Normal	Normal	Normal	Normal	Normal	Normal
	/Affected	/Affected	/Affected	/Affected	/Affected	/Affected	/Affected	/Affected
Pothagam	Normal	Normal	Normal	Normal	Normal	Normal	Normal	Normal
	/Affected	/Affected	/Affected	/Affected	/Affected	/Affected	/Affected	/Affected
Tharpagam	Normal	Normal	Normal	Normal	Normal	Normal	Normal	Normal
	/Affected	/Affected	/Affected	/Affected	/Affected	/Affected	/Affected	/Affected
Santhigam	Normal	Normal	Normal	Normal	Normal	Normal	Normal	Normal
	/Affected	/Affected	/Affected	/Affected	/Affected	/Affected	/Affected	/Affected

10. ENVAGAI THERVU: [EIGHT TYPES OF EXAMINATION]

I. NAADI: [PULSE PERCEPTION]

	NAADI	0 th day	8 th day	15 th day	22 nd day	29 th day	36 th day	43 rd day	49 th day
ſ									

II. SPARISAM: [PALPATION]

Day	SPARISAM
0 th day	
8 th day	
15 th day	
22 nd day	
29 th day	
36 th day	
43 rd day	
49 th day	

III. NAA: [TONGUE]

NAA	0 th day	8 th day	15 th day	22 nd day	29 th day	36 th day	43 rd day	49 th day

IV. NIRAM: [COMPLEXION]

- 1. Vaatham
- 2. Pitham
- 3. Kabam

V. MOZHI: [VOICE]

- 1. High Pitched
- 2. Low Pitched
- 3. Medium Pitched

VI.VIZHI: [EYES]

VIZHI	0 th day	8 th day	15 th day	22 nd day	29 th day	36 th day	43 rd day	49 th day

VII. MALAM: [BOWEL HABITS / STOOLS]

	Before treatment	After treatment
Niram		
Irugal		
Ilagal		
Others		

VIII. MOOTHIRAM [URINE EXAMINATION]

NEERKKURI:

Neerkkuri	Before treatment	After treatment
Niram		
Manam		
Edai		
Nurai		
Enjal		

NEIKKURI:

Neikkuri	Before treatment	After treatment
Aravana needathu/ Snake like pattern		
Azhipol paraviyathu Annular/Ringedpattern		
Muththothu ninrathu Pearlbeadepattern		
Other patterns		

CLINICAL EXAMINATION:

LOCOMOTOR SYSTEM:

CLINICAL SYMPTOMS:

Affected heel:	Right	Left	Both	
Pain in Heel:	Mild	Moderate	Severe	
Onset:	Sudden	Gradual		

CLINICAL EXAMINATION OF HEEL I.INSPECTION:

	0 th day	8 th day	15 th day	22 nd day	29 th day	36 th day	43 rd day	49 th day
Swelling	Present/	Present/	Present/	Present/	Present/	Present/	Present/	Present/
	Absent	Absent	Absent	Absent	Absent	Absent	Absent	Absent
Deformity	Present/	Present/	Present/	Present/	Present/	Present/	Present/	Present/
	Absent	Absent	Absent	Absent	Absent	Absent	Absent	Absent

II.PALPATION:

	0 th day	8 th day	15 th day	22 th day	29 th day	36 th day	43 rd day	49 th day
Tenderness	Present/	Present/	Present/	Present/	Present/	Present/	Present/	Present/
	Absent	Absent	Absent	Absent	Absent	Absent	Absent	Absent
Local heat	Present/	Present/	Present/	Present/	Present/	Present/	Present/	Present/
	Absent	Absent	Absent	Absent	Absent	Absent	Absent	Absent

III. MOVEMENTS

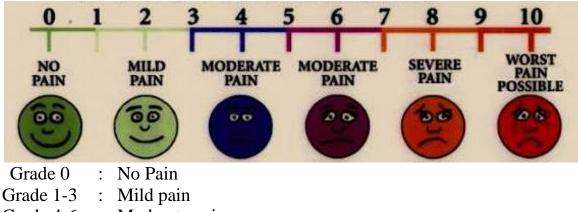
	0 th day	8 th day	15 th day	22 nd day	29 th day	36 th day	43 rd day	49 th day
Dorsi	Normal/	Normal/	Normal/	Normal/	Normal/	Normal/	Normal/	Normal/
Flexion	Affected	Affected	Affected	Affected	Affected	Affected	Affected	Affected
Extension	Normal/	Normal/	Normal/	Normal/	Normal/	Normal/	Normal/	Normal/
	Affected	Affected	Affected	Affected	Affected	Affected	Affected	Affected

IV. JOINT MESUREMENT:

A. HEALTH ASSESSMENT QUESTIONNAIRE:

	0 th day	8 th day	15 th day	22 nd day	29 th day	36 th day	43 rd day	49 th day
PAIN A. Early morning Stiffness								
B. Nature of pain (Mild/ Moderate/ Severe)								
C. Aggravating factor- Movement (Yes/No)								
D. Relieving factor –Rest (Yes/No)								
E. Tenderness (Present/absent)								
RESTRICTION OF MOVEMENT (Fully/Partial/No)								

1. UNIVERSAL PAIN ASSESMENT SCALE:



Grade 4-6 : Moderate pain Grade 7-10 : Severe pain

2. RESTRICTED MOVEMENT ASSESSMENT SCALE:

GRADATION OF MOVEMENTS

GRADE I - Fit for all activities. Can do their work without support
GRADE II - Mild restriction of movements, Mild pain present in heel.
- Moderate restriction of movements, stiffness pain in heel.

GRADE IV - Bed ridden / confined to chair, severe pain.

3. QUESTIONNARIE:

B.

PAIN IN HEEL (Please \sqrt{Mark})

Signs and Symptoms		fore tment	After Treatment		
	Yes	No	Yes	No	
Pain present in getting up in the morning					
Pain present 2 hours after getting up					
Pain present at bedtime					
Pain present throughout the day					
Pain aggravates on standing and walking					
Pain at rest					
Tenderness					
Pain in movements					

Date: Station: Signature of the Investigator: Signature of the Faculty:

Signature of the HOD

DEPARTMENT OF SIRAPPU MARUTHUVAM

AN OPEN CLINICAL TRIAL OF SIDDHA DRUG "AKKINI CHOORANAM" (INTERNAL) AND "VEERA MEZHUGU" (EXTERNAL) IN THE TREATMENT OF "KUTHIKAAL VAATHAM" (PLANTAR FASCIITIS).

Principal Investigator: Dr.M.Padmavathi

1. SERIAL NO: 3. NAME:

2. OP /IP NO: 4. AGE/GENDER:

BLOOD INVES	BLOOD INVESTIGATIONS		BEFORE TREATMENT	AFTER TREATMENT
Hb(gr	n/dl)	M:13-18		
		W:11-16		
		M:4.5-6.5		
T.RBC(millions	cells /Cu.mm)	W:3.5-5.5		
	½ hr.			
ESR (mm)	1 hr.	M:0-10		
	1	W:0-20		
T.WBC (Cel	ls /Cu.mm)	4000-11000		
	Polymorphs	40-75		
	Lymphocytes	20-35		
Differential Count (%)	Monocytes	2-10		
	Eosinophils	1-6		
	Basophils	0-1		

FORM -III - LABORATORY INVESTIGATIONS

BLOOD INVESTIGATIONS		NORMAL VALUES	BEFORE TREATMENT	AFTER TREATMENT
Blood	Fasting	70-110		
glucose (mg/dl)	РР	80-140		
	Serum cholesterol	150-200		
Lipid	HDL	30-60		
profile	LDL	Up to 130		
(mg/dl)	VLDL	40		
	TGL	Up to 160		
RFT	Blood urea	16-50		
(mg/dl)	Serum creatinine	0.6-1.2		
	Total bilirubin	0.2-1.2		
	Direct bilirubin	0.1-0.2		
	Indirect bilirubin	0.2-0.7		
	Total protein	6-8		
LFT (mg/dl)	Serum Albumin	3.5-5.5		
-	Serum globulin	2-3.5		
	SGOT (IU/L)	0-40		
	SGPT (IU/L)	0-35		
	Alkaline phosphatase (IU/L)	80-290		
	Serum calcium	9-11		
	Serum phosphorus	2-5		
	Serum Uric acid	M:3-9		
	CRP			
	ASO titre			
	RA factor			

B.URINE INVESTIGATIONS:

URINE INVESTIGATIONS	BEFORE TREATMENT	AFTER TREATMENT
Albumin		
Sugar (Fasting) (PP)		
Deposits		

C.RADIOLOGICAL EXAMINATIONS

X- Ray: Ankle joint with Heel:

- Antero posterior
 Lateral view

Date: Station: Signature of the Investigator: Signature of the Faculty:

Signature of the HOD

DEPARTMENT OF SIRAPPU MARUTHUVAM

AN OPEN CLINICAL TRIAL OF SIDDHA DRUG "AKKINI CHOORANAM" (INTERNAL) AND "VEERA MEZHUGU" (EXTERNAL) IN THE TREATMENT OF "KUTHIKAAL VAATHAM" (PLANTAR FASCIITIS).

Principal Investigator: Dr.M.Padmavathi

FORM - IV (DRUG COMPLIANCE FORM)

SERIAL NO : OP/IP NO : NAME : AGE/GENDER : DRUGNAME:AKKINI CHOORANAM

Day	Date	Morning	Evening	Day	Date	Morning	Evening
Day 1				Day6			
Day2				Day7			
Day3				Day8			
Day4				Day9			
Day5				Day10			
Day11				Day30			
Day12				Day31			
Day13				Day32			
Day14				Day33			
Day15				Day34			
Day16				Day35			
Day17				Day36			
Day18				Day37			
Day19				Day38			
Day20				Day39			
Day21				Day40			
Day22				Day41			
Day23				Day42			
Day24				Day43			
Day25				Day44			
Day26				Day45			
Day27				Day46			
Day28				Day47			
Day29				Day 48			

Date: Station: Signature of the Investigator: Signature of the Faculty:

Signature of the HOD

DEPARTMENT OF SIRAPPU MARUTHUVAM

AN OPEN CLINICAL STUDY OF SIDDHA DRUG "AKKINI CHOORANAM" (INTERNAL) AND "VEERA MEZHUGU" (EXTERNAL) IN THE TREATMENT OF "KUTHIKAAL VAATHAM" (PLANTAR FASCIITIS).

FORM V – PATIENT INFORMATION SHEET

Name of Principal Investigator: Dr.M.Padmavathi

Name of the institute: National Institute of Siddha, Tambaram Sanatorium, Chennai-47.

INFORMATION SHEET FOR PATIENTS PARTICIPATING IN THE OPEN CLINICAL TRIAL.

I Dr.M.Padmavathi Studying M.D (Siddha) at National Institute of Siddha, Tambaram Sanatorium is doing a clinical trial on KUTHIKAAL VAATHAM (PLANTAR FASCIITIS). In this regard, I am in a need to ask you few questions. I will maintain confidentiality of your comments and data obtained. There will be no risk of disclosing your identity and no physical, psychological or professional risk is involved by taking part in this study. Taking part in this study is voluntary. No compensation will be paid to you for taking part in this study.

You can choose not to take part. You can choose not to answer a specific question. There is no specific benefit for you if you take part in the study. However, taking part in the study may be of benefit to the community, as it may help us to understand the problem of defaulters and potential solutions.

If you agree to be a participant in this study, you will be included in the study primarily by signing the consent form and then you will be given the internal medicine AKKINI CHOORANAM (Internal medicine-1.5gm BD with hot water for 48 days) and VEERA MEZHUGU (External medicine).

The information I am collecting in this study will remain confidential. I will ask you few questions through a questionnaire.

If you wish to find out more about this study before taking part, you can ask me all the questions you want or contact Dr.M.PADMAVATHI PG Scholar, Ph.no:9092146820 cum principal investigator of this study, attached to National Institute of Siddha, Chennai-47. You can also contact the Member-secretary of Ethics committee, National Institute Siddha, Chennai 600047, for rights and participation in the study.

தகவல் படிவம்

நோய்க்கான சித்த மருந்துகளின் **அக்கினி சூரணம்** (உள் மருந்து) மற்றும் **வீர மெழுகு** (வெளி மருந்து) பரிகரிப்புத் திறனைக் கண்டறியும் மருத்துவ ஆய்விற்கான தகவல் படிவம்.

முதன்மை ஆராய்ச்சியாளர் பெயர் : மரு. மா. பத்மாவதி

நிறுவனத்தின் பெயர் : தேசிய சித்த மருத்துவ நிறுவனம் தாம்பரம் சானட்டோரியம் சென்னை- 47

தேசிய சித்த மருத்துவ நிறுவனத்தில் பட்ட மேற்படிப்பு பயின்று வரும் நான் (மருத்துவர்.மா. பத்மாவதி) குதிகால் வாதம் என்னும் நோய்க்கான மருத்துவ ஆராய்ச்சியில் ஈடுபட்டுள்ளேன்.

இது குதிகாலில் வலி, வீக்கம், நடப்பதில் சிரமம்,காலை நேரங்களில் விறைப்புத்தன்மை முதலிய குறிகுணங்களைக் கொண்ட நோய்

இது பரவக் கூடிய நோய் அல்ல.

இந்த ஆராய்ச்சி சம்பந்தமாக சில கேள்விகளைக் கேட்கவும், தேவையான ஆய்வக பரிசோதனைக்கு தங்களை உட்படுத்தவும் உள்ளேன்.

இந்த ஆராய்ச்சிக்கு தாங்கள் விருப்பத்தின் பேரில் உட்படும் பட்சத்தில் உள்மருந்தாக அக்கினி சூரணம் 1.5கிராம் வெந்நீரில் 2 வேளை (காலை மாலை) உணவுக்குப் பின் 48 நாட்களுக்கு உட்கொள்ள வேண்டும். வெளி மருந்தாக வீர மெழுகு 48 நாட்களுக்கு நோயுள்ள -இடங்களில் வெளியே தடவ வேண்டும். வெளி நோயாளர் 7 நாட்களுக்கு ஒருமுறை மருத்துவமனைக்கு வரவேண்டும்.

இது சம்பந்தமான தங்களது அனைத்து விவரங்களும் ரகசியமாக வைக்கப்படும் என உறுதி அளிக்கிறேன். இதில் பயணப்படி முதலிய எந்த உதவி தொகையும் வழங்கப்பட மாட்டாது.

இந்த ஆராய்ச்சியின் போது உடலுக்கு வேறு பாதிப்பு ஏற்படும் பட்சத்தில் தேசிய சித்த மருத்துவமனையில் தக்க மாற்று சிகிச்சை அளிக்கப்படும். இந்த ஆராய்ச்சியில் தங்களை உட்படுத்திய பிறகு உங்களுக்கு விருப்பமில்லையெனில் எப்போது வேண்டுமானாலும் விலகி கொள்ள முழு உரிமை உள்ளது.

இந்த ஆராய்ச்சி சம்பந்தமாக மற்ற விபரங்களுக்கும் நோயின் தன்மை பற்றியும் முதன்மை ஆராய்ச்சியாளரான **மரு. மா. பத்மாவதி (பட்ட** மேற் படிப்பாளர் சிறப்பு மருத்துவ பிரிவு) அணுகவும். கைப்பேசி எண் 9092146820 மேலும் இந்த ஆராய்ச்சிக்கு IEC சான்று பெறப்பட்டுள்ளது.

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DEPARTMENT OF SIRAPPU MARUTHUVAM

AN OPEN CLINICAL TRIAL OF SIDDHA DRUG "AKKINI CHOORANAM" (INTERNAL) AND "VEERA MEZHUGU" (EXTERNAL) IN THE TREATMENT OF "KUTHIKAAL VAATHAM" (PLANTAR FASCIITIS).

Principal Investigator: Dr. M. Padmavathi

CONSENT FORM - FORM VI

"I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions I have asked have been answered to my satisfaction.

I consent voluntarily to participate as a participant in this study and understand that I have the right to withdraw from the study at any time without in any way it affecting my further medical care".

"I have received a copy of the information sheet/consent form".

Date:

Signature of the participant

In case of illiterate participant

"I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm individual has given consent freely."

Date:

Signature of a witness (Selected by the participant bearing no connection with the survey team)



Left thumb Impression of the Participant

FORM VI <u>ஒப்புதல் படிவம்</u> ஆய்வாளரால் சான்றளிக்கப்பட்டது

நான் குதிகால் வாதம் என்னும் நோயின் ஆய்வைக் குறித்த அனைத்து விபரங்களையும் நோயாளிக்குப் புரியும் வகையில் எடுத்துரைத்தேன் என உறுதியளிக்கிறேன்.

தேதி:

கையொப்பம்:

இடம்:

பெயர்:

நோயாளியின் ஒப்புதல்

என்னிடம் ஆய்வின் இந்த மருத்துவ காரணத்தையும், மருந்தின் தன்மை பற்றியும், தொடர்ந்து மற்றும் மருத்துவ வழிமுறை எனது உடல் இயக்கத்தைக் கண்காணிக்கவும், அதனைப் பாதுகாக்கவும் பயன்படும் அய்வுக்கூட மருத்துவ பரிசோதனைகள் பற்றி திருப்தி அளிக்கும் வகையில் ஆய்வு விளக்கிக் மருத்துவரால் கூறப்பட்டது.

நான் இந்த மருத்துவ ஆய்வின் போது, காரணம் எதுவும் கூறாமல், எப்பொழுது வேண்டுமானாலும் இந்த ஆய்விலிருந்து என்னை விடுவித்து கொள்ளும் உரிமையைத் தெரிந்திருக்கின்றேன்.

சுதந்திரமாகத் தேர்வு செய்யும் உரிமையைக் கொண்டு நான் என்னுடைய குதிகால் வாதம் என்னும் நோய்க்கு அக்கினி சூரணம் (உள் மருந்து) மற்றும் வீர மெழுகு (வெளி மருந்து) மருந்தின் பரிகரிப்புத் கண்டறியும் திறனைக் மருத்துவ ஆய்விற்கு என்னை உட்படுத்த ஒப்புதல் அளிக்கிறேன்.

தேதி:

இடம்:

கையொப்பம்: பெயர்: சாட்சிக்காரர் கையொப்பம்: பெயர்: உறவுமுறை:

விரிவுரையாளார் கையொப்பம்:

துறைத்தலைவர் கையொப்பம்:

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DEPARTMENT OF SIRAPPU MARUTHUVAM

AN OPEN CLINICAL STUDY OF SIDDHA DRUG "AKKINI CHOORANAM" (INTERNAL) AND "VEERA MEZHUGU" (EXTERNAL) IN THE TREATMENT OF "KUTHIKAAL VAATHAM" (PLANTAR FASCIITIS).

Principal Investigator: Dr.M.Padmavathi

FORM VII - WITHDRAWAL FORM

1. SERIAL NO OF THE CASE: 2. OP / IP NO: 3. NAME: **4.AGE:** 5.GENDER:..... 6. DATE OF TRIAL COMMENCEMENT: 7. DATE OF WITHDRAWAL FROM TRIAL: 8. REASONS FOR WITHDRAWAL: Long absence at reporting: Yes/No Irregular treatment: Yes/No Shift of locality: Yes/No Increase in severity of symptoms: Yes/No Development of severe adverse drug reactions: Yes/No Development of adverse event: Yes/No

(If YES, give the details of adverse reaction in Form IX – Adverse Reaction Form / Pharmaco Vigilance Form)

Date:

Station:

Signature of the Investigator:

Signature of the Faculty:

Signature of the HOD

DEPARTMENT OF SIRAPPU MARUTHUVAM

AN OPEN CLINICAL TRIAL OF SIDDHA DRUG "AKKINI CHOORANAM" (INTERNAL) AND "VEERA MEZHUGU" (EXTERNAL) IN THE TREATMENT OF "KUTHIKAAL VAATHAM" (PLANTAR FASCIITIS).

Principal Investigator: Dr.M.Padmavathi FORM – VIII DIETARY ADVICE FORM

சேர்க்க கூடிய உணவுகள்	தவிர்க்க வேண்டியவைகள்
காய்கள் (Vegetables): கத்தரிப்பிஞ்சு (Unripe brinjal) முருங்கைப்பிஞ்சு (Unripe drumstick) அவரைப்பிஞ்சு (Unripe Dolichos bean) கீரைகள்(Greens): பொன்னாங்கண்ணி (Sessile plant [<i>Alternanthera sessilis</i>]) மூக்கிரட்டை (Hog weed [<i>Boerhaavia diffusa</i>]) தூதுவேளை (Climbing brinjal [<i>Solanum</i> <i>trilobatum</i>]) முருங்கைக்கீரை (Leaves of Drumstick [<i>Moringa</i> <i>oleifera</i>]) கறிவேப்பிலை (Curry leaf [<i>Murraya koenigii</i>]) முடக்கறுத்தான் (Winter cherry [<i>Cardiospermum halicacabum</i>]) அறுகீரை (<i>Amaranthus tristis</i>) கரிசாலை (trailing eclipta [Eclipta prostrate]) பழங்கள்(Fruits): மாதுளை (Pomegranate) ஆப்பிள் (Apple) பப்பாளி (Papaya) ஆரஞ்சு (Orange) பேரீச்சை (Dates) அத்தி (Fig) நாவல் (Jambul [<i>Syzygium cumini</i>]) அசைவம் (Non-vegetarian diet): வெள்ளாட்டுக்கறி (Meat) காடை (Quail) , சிறு இறால்மீன் (Prawn)	சனர (Bottle gourd) பூசனி (Pumpkin) வெள்ளரிக்காய் (Cucumber) புடலை (Snake gourd) உளுந்து (Black gram) மொச்சை (Indian butter Bean) காராமணி (Cow gram) கொள்ளு (Horse gram) கடுகு (Mustard) எண்ணெய் (Gingelly oil) புளிப்பு (Sour) உப்பு (Salt) வாயுப் பொருட்கள் (Vatha diet) உருளைக் கிழங்கு (Potato) வாழைக் காய் (Plantain) புகையிலை (Tobacco) மது அருந்துதல் (Alcohol) பெண்போகம் (இச்சா பத்தியம்) [Sexual intercourse]

மருத்துவ அறிவுரை:

ஈரமில்லாத் தரையிலும், படுக்கையிலும் படுத்தல் வேண்டும், குளிர் காற்று படும்படியான இடத்தில் இருப்பதைத் தவிர்க்கவும். உடல் அதிக எடை இருப்பின் எடையைக் குறைக்க வேண்டும். அதிக தூரம் நடத்தல், அதிக நேரம் நிற்றல் தவிர்க்கவும்

DEPARTMENT OF SIRAPPU MARUTHUVAM

AN OPEN CLINICAL TRIAL OF SIDDHA DRUG "AKKINI CHOORANAM" (INTERNAL) AND "VEERA MEZHUGU" (EXTERNAL) IN THE TREATMENT OF "KUTHIKAAL VAATHAM" (PLANTAR FASCIITIS).

Name of Principal Investigator: Dr.M. Padmavathi

FORM IX – ADVERSE REACTION FORM / PHARMACO VIGILANCE FORM

SERIAL NO:

OP/IP NO:

NAME:

AGE:

GENDER:

DATE OF TRIAL COMMENCEMENT:

DATE OF THE ADVERSE REACTION OCCUR:

DESCRIPTION OF ADVERSE REACTION:

Date: Station: Signature of the Investigator: Signature of the Faculty:

Signature of the HOD

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